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MAXIMIZING SECURITY BENEFITS FROM TECHNICAL COOPERATION IN MICROBIOLOGY AND BIOTECHNOLOGY

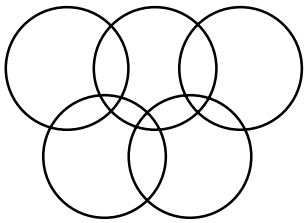
by Graham S. Pearson

REPORT* OF THE NATO ADVANCED RESEARCH WORKSHOP PIESTANY, SLOVAKIA: 18 - 20 MAY 2000

Introduction

1. The NATO Advanced Research Workshop entitled "Maximizing the Security Benefits from International Cooperation in Microbiology and Biotechnology" was held in Piestany, Slovakia on Thursday 18 through Saturday 20 May 2000 under the co-directorship of Dr Cyril Klement, State Institute of Public Health, Slovakia, and Professor Graham Pearson, Visiting Professor of International Security in the Department of Peace Studies in the University of Bradford, UK. It was attended by 40 individuals, of which 28 came from 9 NATO countries (Belgium, Czech Republic, France, Hungary, Italy, Netherlands, Poland, United Kingdom and United States) including representatives from the European Commission (EC), the International Centre for Genetic Engineering and Biotechnology (ICGEB) and one from the Organization for the Prohibition of Chemical Weapons (OPCW), 11 from 4 Partner countries (Romania, the Russian Federation, Slovakia and Ukraine) and one from Sweden. Nine of the experts, from 8 countries, attending the Piestany workshop are members of the delegations attending the Ad Hoc Group in Geneva.

2. The workshop was designed to focus on how the benefits to security from international cooperation in microbiology and biotechnology might be maximized under Article VII "Scientific and Technological Exchange and International Cooperation" of the Protocol being negotiated by the Ad Hoc Group (AHG) in Geneva to strengthen the Biological and Toxin Weapons Convention (BTWC). The Workshop brought together a wider range of different clusters of experts, many of whom met for the first time at the Workshop. Indeed, the Olympic symbol:



visually indicates the way in which the different clusters of experts -- in microbiology, biotechnology, biosafety, the Chemical Weapons Convention and the Protocol on the Biological Weapons Convention -- came together very effectively to share their ideas and experience on issues relating to the Workshop theme. The presentations and discussion really moved forward our collective appreciation as to how indeed security benefits could be

* This report is based on 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 highly effective and enjoyable Workshop.

maximised through technical collaboration in microbiology and biotechnology in a world that is increasingly looking for safety, improved health and greater prosperity.

3. The Piestany ARW was structured to enable discussion of the issues relating to international cooperation in microbiology and biotechnology in such a way so that the experience gained under ongoing technical collaboration could be analyzed so as to address how the benefits to security might be maximized in the context of Article VII of the Protocol to the Biological and Toxin Weapons Convention. The workshop had five main sessions:

Session I. Security Implications of Microbiology and Biotechnology. The first session set the scene for the workshop by outlining the background to the ongoing negotiations of a Protocol to strengthen the Biological and Toxin Weapons Convention and showing how there was close relevance to international developments in both biosafety and Good Manufacturing Practice. The potential dangers from developments in microbiology and biotechnology was then examined and the way in which the Pathogens Initiative programme had reduced these dangers in institutes in Russia was addressed by presentations covering a Russian and a USA perspective.

Session II. Benefits from International Cooperation in Microbiology and Biotechnology. Overviews of ongoing international collaboration in microbiology and biotechnology were provided by presentations by participants from Germany and the ICGEB. An overview was also provided of the European Commission research programme on the "Quality of Life and Management of Living Resources" with countries outside the EU. Particular attention was given to biosafety with a presentation on the ongoing Netherlands programme to implement biosafety frameworks in the pre-accession countries of Central and Eastern Europe and a presentation by a representative from the Russian Federation. In addition, Good Manufacturing Practice for licensed pharmaceutical and biological products was examined with presentations by participants from Romania and the Russian Federation.

Session III. Implementation of Article X of the BTWC which promotes technical cooperation between the States Parties. The opening presentations in this session addressed the importance of urgently strengthening the Convention given by a participant from Hungary and the role that technical cooperation to aid the development of States Parties could have within the Protocol in improving security given by a participant from the UK. These were then followed by a series of presentations about international collaboration in the field of microbiology and biotechnology between developed and developing countries in which the lessons learnt from such collaboration were identified; these presentations were made by participants from the UK, Slovakia, the Czech Republic and Poland.

Session IV. Maximizing Security Benefits. An overview presentation examined how the security benefits under the BTWC Protocol might be maximized by technical cooperation given by a participant from the Netherlands. This was followed by presentations on infrastructure, regulations and procedures by participants from the UK, Slovakia and France, on databases, communications networks and clearing houses by a participant from the USA, on the OPCW experience of international cooperation and assistance by a participant from the OPCW and finally a presentation on transfers of microbiological materials by a participant from the USA.

Session V. Maximizing BTWC Protocol Security Benefits from Technical Cooperation. The final session was a summary presentation by one of the co-Directors of the Workshop in which a personal appreciation of the outcome of the Workshop in regard to its theme of maximizing security benefits through international collaboration in microbiology and biotechnology was presented.

4. Overall, the Workshop was extremely timely as it enabled the participants who brought a wide range of expertise in different areas to have an outstandingly informed discussion about the contribution that scientific and technological exchange and international collaboration in the context of Article VII of the future Protocol can make towards the strengthening of the Biological and Toxin Weapons Convention. The participation of representatives from the ICGEB and the OPCW in the Workshop was especially valuable as it provided the opportunity for all participants to gain a first hand insight into the work of these organizations and the way in which their work is evolving.

5. The workshop brought together experts engaged in a number of different areas:

- International technical cooperation in microbiology and biotechnology;
- Implementation of the biosafety aspects of the Convention on Biological Diversity, the UNEP International Guidelines on Biosafety, and the very recently finalized Cartagena Protocol on Biosafety;
- Good Manufacturing Practice of pharmaceutical and biological products;
- Implementation of international cooperation and assistance under the OPCW; and,
- A Protocol to strengthen the Biological and Toxin Weapons Convention.

The key points emerging from the presentations and discussion in each of these areas is considered in turn.

International Technical Cooperation in Microbiology and Biotechnology

6. The Earth Summit held in Rio de Janeiro in June 1992 saw the agreement of the Rio Declaration on Environment and Development with a number of Principles and of Agenda 21 which addressed the pressing problems of today and also aims at preparing the world for the challenges of the 21st century[1]. Chapter 16 of Agenda 21 addresses *"Environmentally sound management of biotechnology"* with five principal areas:

A *Increasing the availability of food, feed and renewable resources*
B *Improving human health*
C *Enhancing protection of the environment*
D *Enhancing safety and developing international mechanisms for cooperation*
E *Establishing enabling mechanisms for the development and the environmentally sound application of biotechnology.*

[1]Further details about Agenda 21 and the Convention on Biological Diversity are provided in Graham S. Pearson, *Article X: Some Building Blocks*, University of Bradford, Department of Peace Studies, Briefing Paper No. 6, March 1998. Available at http://www.brad.ac.uk/acad/sbtwc

The objectives and activities outlined in Chapter 16 of Agenda 21 embrace a very wide range of collaborative and cooperative activities in biotechnology.

7. The requirements for technical cooperation in biotechnology in developing countries can be summarised under the headings of technical and infrastructure:

Technical

- Acquisition of Technology
- Establishment of Critical Mass
- Access to Information
    - Technical
    - Commercial
- Development of Natural Resources
    - In-Country
    - Value-Added
- Biosafety Regime
- Patent Regime

Infrastructure

- Project Prioritization
- Project Management
- Industrial Infrastructure
- Globalization Issues
    - Treaties and Convention (IPR, CBD)
- Political Will
- Public Acceptance
- Risk Assessment and Risk Management

Particular points to note were that:

- Developing countries are seeking **cutting-edge** technology.
- The biotechnology information required by developing countries is the **same** as that required by developed countries.
- Establishment of critical mass is key to success -- limiting factor is **training**.
-The **training** and the skills needed to enable proposals of a standard acceptable for funding to be prepared.
- Small targetted **training** grants are cost-effective.
- Project prioritization is of vital importance --
  and has to be done by the **developing** country
  together with long-term commitment.

8. The considerations that need to be addressed for successful biotechnology cooperation are:

1. Clear objectives and ground rules
2. Capacity building
    - Personnel, facilities and materials
3. Availability of staff

4. Communications
    - In-country
    - Internet
    - Access to scientific information in journals, books and libraries
5. Continuity
6. Conservation
    - Biodiversity, degradation
    - Value-added
7. Transparency
    - Awareness of cultural differences
    - Publicity and publications
8. Realism

9. It was noted that whilst there is a great deal of detailed microbiology and biotechnology information now available on the internet, there are considerable difficulties in finding the information and in evaluating the quality of the information. Increasingly, new information is being protected by copyright and by patents and there are difficulties in gaining access to some of this information. Some websites provide massive amounts of information but without providing any guidance to the sites or any contacts from whom further information can be obtained. There was a clear need for an analytical element on internet based databases which provided advice as to how to find reliable, quality information and essentially provided "route maps" to other websites.

10. The International Centre for Genetic Engineering and Biotechnology (ICGEB) with an annual budget of $14 M is engaged on a number of capacity building activities in its Member States and has a research programme with two main areas:

Human Health

- Infectious Diseases
- Vaccine Protection
- Genetic Diseases

Plant Biology

- Plant Transformation
- Stress Resistance
- Crop Improvement

In addition, ICGEB in its Advisory Services provides assistance in the formulation of national bioscience policies, the definition of research goals, innovative patent policies and the establishment of national biotechnology laboratories. Two particularly important activities in respect of international cooperation are:

- The ICGEB Biotechnology Information Sharing System (BISS) which provides a comprehensive mechanism allowing a continuous flow of information on

    1. Biosafety
    2. R & D activities in ICGEB Member States
    3. Industrial Development
    4. Quality Control, Harmonization and Implementation of GMP and GLP

• The ICGEB Biosafety Unit which disseminates information through its biosafety database[2] and aids capacity building through

- Annual biosafety workshops (since 1992)
- UNEP/GEF "Pilot Biosafety Enabling Activity Project"
- Cooperation and training with Member State biosafety authorities in biosafety and risk assessment.

There is clearly a potential role of the ICGEB in the implementation of the biosafety initiatives under the Convention on Biological Diversity and of the future BTWC Protocol although not all ICGEB Member States are States Parties to the BTWC.

11. The European Commission has a significant research programme on the Quality of Life and Management of Living Resources Programme[3] (Fifth Framework Programme 1999 - 2002) which under Activity 2 "Confirming the International Role of Community Research" has a budget of 475 M Euro divided into the following categories of cooperation with third countries[4]:

1. Pre-accession states	26
2. NIS and other CEECs	112
3. Mediterranean partners	55
4. Developing countries	210
5. Emerging economy countries and industrialised countries	5
6. Training of researchers	15
7. Coordination	52
Total	475

12. In discussion of international cooperation in microbiology and biotechnology, the question of whether aid should be conditional was raised. It was noted that some countries, such as the UK, claimed to have an ethical foreign policy. This led to the idea that aid should be conditional on those States having acceded to the international treaties that establish international norms -- such as the BTWC or the Convention on Biological Diversity -- and that if States have not acceded then aid should be provided to enable States to accede to these treaties.

Biosafety

13. The programme area *"**D** Enhancing safety and developing international mechanisms for cooperation"* under Agenda 21 includes a number of specific activities which include:

[2]See for example, the ICGEB Biosafety Web Pages at http://www.icgeb.trieste.it/biosafety/bsfmain.htm

[3]Information on the Quality of Life and Management of Living Resources Programme is available at http://europa.eu.int/comm/research/quality-of-life.html

[4]Budget information is available at http://www.cordis.lu/fp5/src/budget5.htm

Compile, update and develop compatible safety procedures into a framework of internationally agreed principles as a basis for guidelines to be applied on safety in biotechnology, including consideration of the need for and the feasibility of an international agreement, and promote information exchange as a basis for further development, drawing upon the work already undertaken by international and other expert bodies.

It is this that has led to the development and agreement of the UNEP International Guidelines on Biosafety and then to the negotiation completed in January 2000 of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity (CBD)[5].

14. An extensive programme of capacity building in biosafety is being carried out by the Netherlands government under a three year $700,000 Matra Project "Implementation of National Biosafety Frameworks in the Countries of Central and Eastern Europe." This programme is directed at the pre-EC accession States of Central & Eastern Europe and has four key elements:

- Regulatory Framework
- Administrative System
- Decision Making (Risk Assessment)
- Information

National biosafety frameworks frequently address both pathogenic microorganisms and genetically modified organisms and often include the establishment of a competent national authority which will carry out inspections of national facilities.

15. It was evident that the momentum for this programme comes from the governments of the countries which wish to accede to the European Community and need to have the necessary legislation, regulations and infrastructure in place. It was clear that all States in Europe and in Central & Eastern Europe were engaged in the setting up of the necessary biosafety infrastructure which would result in:

- competent national authority and national inspections
- over time increased transparency and building of confidence
- contributions to international safety, health and security

as pathogens and GMOs know no boundaries

Whereas the driver for the Central & Eastern European countries is, among others, to join the EU and thereby to comply with EU regulations, the driver for Africa, Latin America and the Caribbean, and Asia could be the wish to rapidly implement the obligations of the Biosafety protocol.

16. It was also noted that for biosafety regulations to be credible, it was essential that these focussed on the crucial requirements.

[5]Further details about UNEP International Guidelines on Biosafety and the international initiatives in biosafety are provided in Graham S. Pearson, *Article X: Some Building Blocks*, University of Bradford, Department of Peace Studies, Briefing Paper No. 6, March 1998. Available at http://www.brad.ac.uk/acad/sbtwc

Good Manufacturing Practice

17. Good Manufacturing Practice (GMP) was another area that was being addressed by those engaged in the production of licensed pharmaceutical and biological products in the pre-EC accession States of Central and Eastern Europe who needed to reach standards acceptable by EMEA (European Medicines Evaluation Agency). This required the provision of a documented audit trail and controlled processes as well as a national authority which set standards and carried out inspections to ensure products were both reproducible and safe.

18. It was recognized that for international trade in pharmaceuticals and biologicals, GMP to international standards validated by international inspections needed to be adopted by the production facilities concerned. Increasingly, these international standards are being harmonized notably between EMEA, FDA (Food & Drug Administration in the USA) and Japan so as to increasingly provide a level playing field for international trade in products that are internationally acceptable as being safe and reproducible[6].

19. There is a real opportunity for the developing world **provided** that GMP facilities to validated international standards and full recognition of IPR (intellectual property rights) has been achieved. In particular, the low priced producer in a developing country is best placed to make profits especially in manufacture of generic biotechnology drugs which are emerging from their period of patent protection. It was also noted that the consumer in the developing world will **not** tolerate a second rate product for much longer.

20. The risk to the Convention is minimal from those production facilities engaged in licensed product manufacture that have GMP to these validated international standards.

21. There is no comparable coordinated approach to introducing GMP to the EMEA standard to the ongoing biosafety capacity building initiative in the pre-EC accession States in Central & Eastern Europe. Nor are there parallel drivers in other regions of the world such as Africa, Latin America and the Caribbean, or Asia.

22. Achievement of GMP to validated international standards depends on resources with the skills and training to be able to write meaningful process documentation. There appeared to be a need for an international clearing house on validated GMP standards and the extent to which these are increasingly being harmonized internationally.

23. It was again noted that as in the case of biosafety, for GMP regulations to be credible, it was essential that these focussed on the crucial requirements.

International Cooperation and Assistance under the OPCW

24. The Chemical Weapons Convention provides a balance between the rights and obligations of States Parties through its provisions on Assistance, Protection and International Cooperation for the economic and technological development of States Parties. Currently the International Cooperation and Assistance Division of the OPCW (Organization for the

[6]Information about Good Manufacturing Practice and international harmonization is provided in Graham S. Pearson, *Article X: Pharmaceutical Building Blocks*, University of Bradford, Department of Peace Studies, Briefing Paper No. 8, July 1998. Available at http://www.brad.ac.uk/acad/sbtwc

Prohibition of Chemical Weapons) has a strength of 15 and a budget of 5% of that of the Organization ($60 M) ie about $3M.

25. Article XI Economic and Technological Development of the CWC was a provision to ensure universality of the Convention and the contents and scope of Article XI were broader than in previous similar Conventions such as the BTWC of 1972 and the Environmental Modification (ENMOD) Convention of 1977. Article XI of the CWC is developed from the ninth paragraph of the Preamble to the CWC which states that:

> *Desiring to promote free trade in chemicals as well as international cooperation and exchange of scientific and technical exchange in the field of chemical activities for purposes not prohibited under this Convention in order to enhance the economic and technological development of all States Parties*

26. Examples of Article XI activities include:

> • Providing administrative and technical support for National Authorities and other implementation assistance,
> • Supporting capacity building in Member States in areas relevant to the implementation of the Convention,
> • Facilitating exchanges of chemicals, equipment and scientific and technical information relating to the development and application of chemistry for purposes not prohibited under the Convention.

27. **Technical support for National Authorities** has included training courses for personnel of national authorities, a declaration support programme aimed at assisting National Authorities to prepare their OPCW declarations and regional implementation workshops to address implementation issues.

28. **Capacity building in Member States** includes support for national laboratories relevant for the Convention such as improving technical capabilities in analytical laboratories seeking OPCW designation and an analytical symposium for laboratories considering participation in OPCW proficiency testing.

29. **Exchange of chemicals, materials and scientific and technical information** has included conference attendance and internship support programmes providing support to enable scientists and engineers from developing countries and from countries with economies in transitions which are States Parties to attend international meetings in the fields of chemistry and chemical technology or in other areas relevant to the implementation of the Convention. Under this programme more than 90 scientists over the past three years have attended international conferences on subjects such as natural products chemistry, analytical chemistry, destruction of toxic materials, risk assessment and management with respect to toxic materials, environmental chemistry and toxicology, and treatment of intoxications and topics related to the implementation of the Convention.

30. Future plans are to refocus and consolidate the conference support activities in order to ensure the maximum benefits so that in future instead of providing support to individuals, the programme will support institutions or recognized scientific organizations in Member States to organize conferences, seminars or other kinds of meetings on a relevant subject.

31. Internship programmes are aimed at helping scientists and engineers from developing countries or countries with economies in transition to gain experience by working for a period at an advanced research institute. This will also help to establish links and joint research programmes between research groups in developing and industrialized countries.

Scientific and Technological Exchanges and International Cooperation in the BTWC Protocol

32. It was noted that the mandate for the Ad Hoc Group negotiating the Protocol to *strengthen the effectiveness and improve the implementation of the Convention* specifically includes the requirement that the Ad Hoc Group shall consider *inter alia "Specific measures designed to ensure the effective and full implementation of Article X"* of the Convention. This Article places the following obligation on each State Party to the Convention:

> *1. The States Parties to this Convention undertake to facilitate, and have the right to participate in, the fullest possible exchange of equipment, materials, and scientific and technological information for the use of bacteriological (biological) agents and toxins for peaceful purposes. Parties to the Convention in a position to do so shall also cooperate in contributing individually or together with other States or international organisations to the further development and application of scientific discoveries in the field of bacteriology (biology) for the prevention of disease, or for other peaceful purposes.*
>
> *2. This Convention shall be implemented in a manner designed to avoid hampering the economic or technological development of States Parties to the Convention or international cooperation in the field of peaceful bacteriological (biological) activities, including the international exchange of bacteriological (biological) agents and toxins and equipment for the processing, use or production of bacteriological (biological) agents and toxins for peaceful purposes in accordance with the provisions of the Convention.*

33. Article VII of the Protocol, which is largely free of square brackets, has 8 sections and occupies 13 pages (in contrast to the single page Article XI Economic and Technological Development in the CWC). Its sections include:

> (A) General Provisions
> (B) Measures to Promote Scientific and Technological Exchange
> (C) Measures to Avoid Hampering the Economic and Technological Development of States Parties
> (D) Institutional Mechanisms for International Cooperation and Protocol Implementation Assistance
> (E) [Review of][Consideration of Concerns Related to] the Implementation of Article X of the Convention and this Article
> (F) Cooperative relationships with Other International Organizations and Among States Parties
> [(G) Safeguards
> (H) Declarations

34. Particular attention was drawn to Section (F) which lists a range of cooperative relationships in order to, inter alia:

(a) Derive the greatest possible synergy in, and benefits from:

(i) The collection and dissemination of information on the peaceful uses of biological agents and toxins
(ii) Sharing information on environmental release of genetically modified organisms;
(iii) Current Good Manufacturing Practices (GMP), Good Laboratory Practice (GLP), biological containment and other biosafety regulations and practices;
(iv) Facilitation of access to databases containing information on the peaceful uses of bacteriological (biological) agents and toxins, biosafety, and results of scientific research in the life sciences in areas of particular relevance to the Convention;
(v) The collection and dissemination of information on the diagnosis, surveillance, detection, treatment and prevention of diseases caused by biological agents or toxins, in particular infectious diseases;
(vi) Regulations governing the handling, transportation, use and release of bacteriological (biological) agents and toxins;

Several of these were discussed in various contributions to the Workshop.

35. In setting the scene for this session it was noted that:

- The provisions already incorporated into Article VII of the Protocol cover a wide range of measures to promote scientific and technological exchange and technical cooperation for peaceful purposes.
- There is considerable potential for overlap with ongoing technical cooperation under other auspices
- It will be important for the future Protocol Organization **to focus on those cooperative activities for which it is best suited**.
- Article VII measures will bring benefits to all States Parties **and** will over time increase transparency and build confidence.
- The Workshop could usefully identify areas, topics and capability gaps that the future Protocol Organization would appear to be well fitted to address.

36. Attention was drawn to the statement made during the March Ad Hoc Group session by the Minister of Foreign Affairs of The Netherlands that:

> *We must endeavour to further the development by all states, great or small, east or west, north or south, of the benefits that can be brought to them through peaceful uses of biotechnology...But keeping in mind the downside of the developments in biotechnology, we must also redouble our efforts to take measures to prevent the spread of biotechnology for non-peaceful purposes.*

Consequently in considering how to maximize the security benefits, it was equally important to consider how to minimize the risks.

37. Security benefits from international cooperation could come from:

- improving public health

- improving food supplies (poverty alleviation)
- enhancing transparency
- building confidence
- assisting conversion activities
- providing implementation assistance

38. Criteria which might be applied in the evaluation of suggestions for international cooperation could include:

- Contribute to other aspects of protocol implementation
- Promotion of Protocol universality
- Synergies (avoiding unnecessary duplication)
- "Acceptability"
- Cost-effectiveness

39. Particular benefits from the Workshop would come from the identification of concrete suggestions for technical cooperation activities to be carried out under the future BTWC Protocol Organization and from recommendations of how to raise the awareness amongst the negotiators of the Protocol of what is already being done in other fora.

40. Databases were already included in Protocol with language that *Each States Party shall promote and support ... the establishment, operation and updating of biological data bases including those maintained by the Technical Secretariat on information relevant to the purposes of the Convention as well as accessibility to such data bases.* This echoed the words in the Final Declaration of the Fourth Review Conference which said that *The Conference considers that a world-wide data bank might be a suitable way of facilitating the flow of information in the field of genetic engineering, biotechnology and other scientific developments.*

41. Data bases are essential for both biotechnology and for disease control. These data bases are almost always accessed from the web and it would consequently be logical that any data base under the BTWC Protocol should likewise be accessed from the web. It was also noted that e-mail is now an essential communication and collaboration tool. A particular concrete example of benefits from technical cooperation would be through the future BTWC Protocol Organization fostering and promoting internet connectivity both within and between States Parties and the Organization.

42. There is already a huge amount of relevant information on the web. A problem is finding the information and evaluating its reliability and quality. There is a particular need for "road maps/guide books" providing advice on how to find reliable data in quality web sites. In order to use the information available on the web, the following are necessary:

- Access
- Expertise and experience
- Infrastructure

43. It was noted that the Convention on Biological Diversity in Article 18 includes the requirement that *"The Conference of the Parties at its first meeting, shall determine how to establish a clearing house mechanism to promote and facilitate technical and scientific cooperation."* This mechanism has been set up by the Convention on Biological Diversity

with the objective of the clearing house mechanism being *to promote and facilitate technical and scientific cooperation for the implementation ... of the Convention ... by:*

- Human resource and institution development
- Facilitating technology transfer
- Joint ventures research programs

Furthermore, in the early stages of its implementation, the clearing house mechanism should focus on:

- Exchanging and disseminating information
- Creating a directory of services
- Training for effective participation in the CHM (clearing house mechanism) and for technology transfer
- Promoting the establishment of partnerships

The advantages of the clearing house mechanism are the following:

- Facilitates access to information and advice
- Addresses bilateral as well as multilateral projects
- Is a bottom-up, needs-based mechanism

44. There is much that can be learnt from the Convention on Biological Diversity by the future Protocol Organization about the setting up and operation of a clearing house mechanism. A further concrete example of benefits from technical cooperation would be through the future BTWC Protocol Organization establishing a clearing house mechanism addressing information and projects of relevance to the BTWC and its Protocol.

45. Insofar as the Protocol Organization is concerned, the need will be for its web site to contain links to existing databases, preferably with guidance as to how to find information in these existing databases, and for the Organization to establish its own data bases on subjects which are not available or adequately available elsewhere. One example, that can be identified from the experience of the OPCW, is a data base providing information on national legislations, regulations and administrative measures related to the BTWC Protocol; such a data base would be valuable in providing transparency to other States Parties enabling them to review their own national measures and help States Parties implement the Protocol.

General Observations

46. During the Workshop there was also discussion of a number of topics which fell outside those addressed above or which gradually emerged from the discussion and debate. These included the following.

47. **BTWC Protocol.** The BTWC together with a strong Protocol both strengthen the elimination of biological weapons from States Parties and reduce the risk of bioterrorism. The greatest danger of bioterrorism was seen as coming from State sponsored terrorists -- the Convention and the Protocol are counters to States deciding to retain biological weapons as an option. In addition, national implementation of the Convention and the Protocol requirements for national penal legislation make it a criminal offence for any individual to work on biological weapons -- and provides another counter to bioterrorism.

48. An effective Protocol needs to:

- Reinforce the standard of behaviour -- to underline the international norm
- Contain mechanisms to implement the general purpose criterion
- Have a structure of rules and procedures which are taken seriously by States Parties.

The negotiation of the Protocol was nearing completion. There were now islands of brackets in oceans of clean text.

49. **Transfers.** An international survey was being carried out into the procedures currently applied to the transfer of microorganisms from one culture collection to another although it was noted that virtually any microbiology laboratory had its own individual collection of microorganisms and that scientists would frequently exchange microorganisms with other scientists. Nevertheless, the USA in its 'select agent' programme administered by CD addressing the storage, handling and transfer within the USA of a list of dangerous pathogens which were of concern in the context of bioterrorism and the American Type Culture Collection (ACT) in its internal controls provided useful models which could with advantage be extended regionally and internationally. Furthermore, the recently agreed Cartagena Protocol on Biosafety to the Convention on Biological Diversity would lead to implementation of Advanced Informed Agreement for transborder transfers of GMOs (genetically modified organisms). It was evident that transfer controls do contribute to safety, health and security as pathogens and know no boundaries.

50. **Public Awareness.** It was important that those working in microbiology and biotechnology as well as the public are aware of the emerging Protocol regime. One reason for this was because of the importance of the general purpose criterion to the effective implementation of the Convention and the Protocol. It is those working at the cutting edge of microbiology and biotechnology who need to be aware of the comprehensive prohibition and to be able to alert National Authorities when appropriate.

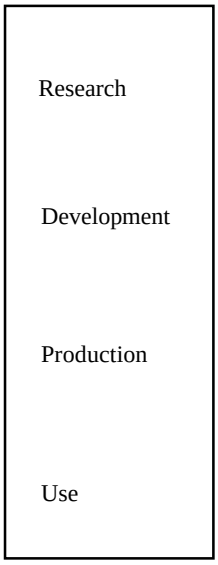
51. It was noted that a people's data base has been suggested which would contain a simple brief description of international treaties and provide links to specialist data bases. Furthermore, it was apparent that comprehensive knowledge of the location and organization of microbiological laboratories within countries together with national accreditation and inspection authorities significantly increases transparency and builds confidence.

52. The optimum time to raise the awareness of specialists and the public would be after the Protocol had been opened for signature. The emphasis now must be on the early completion of the Protocol.

Maximizing BTWC Protocol Security Benefits from Technical Cooperation.

53. In a final presentation the different elements which had been addressed during the Workshop were brought together in an appreciation of how the BTWC Protocol security benefits might be maximized through technical cooperation in microbiology and biotechnology.

54. It was recognised that activities in microbiology and biotechnology taking place within a country with no transparency resulted in a situation:



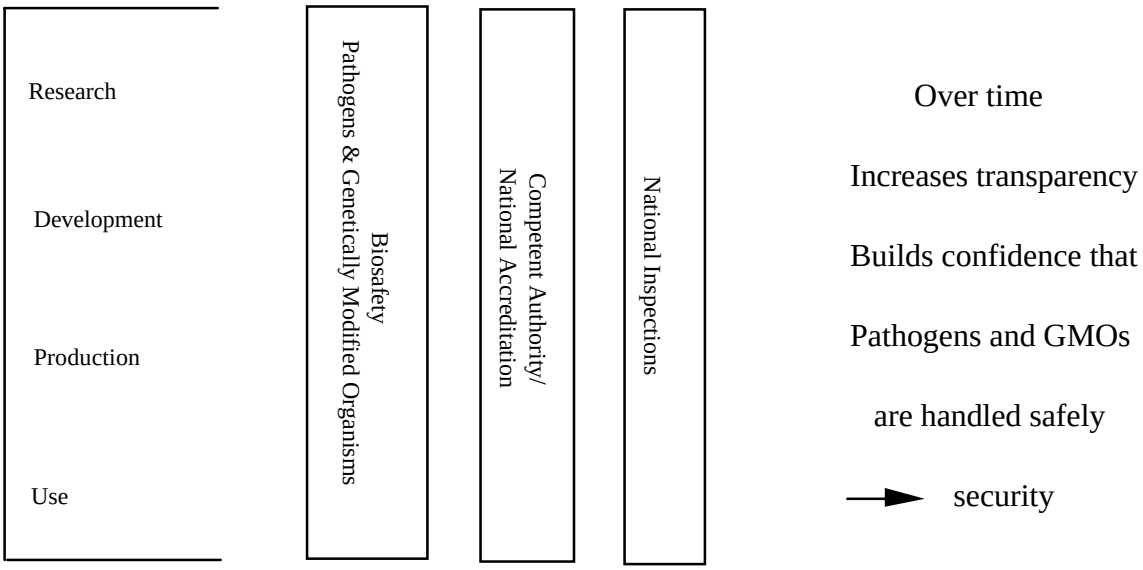
In a black box

this creates

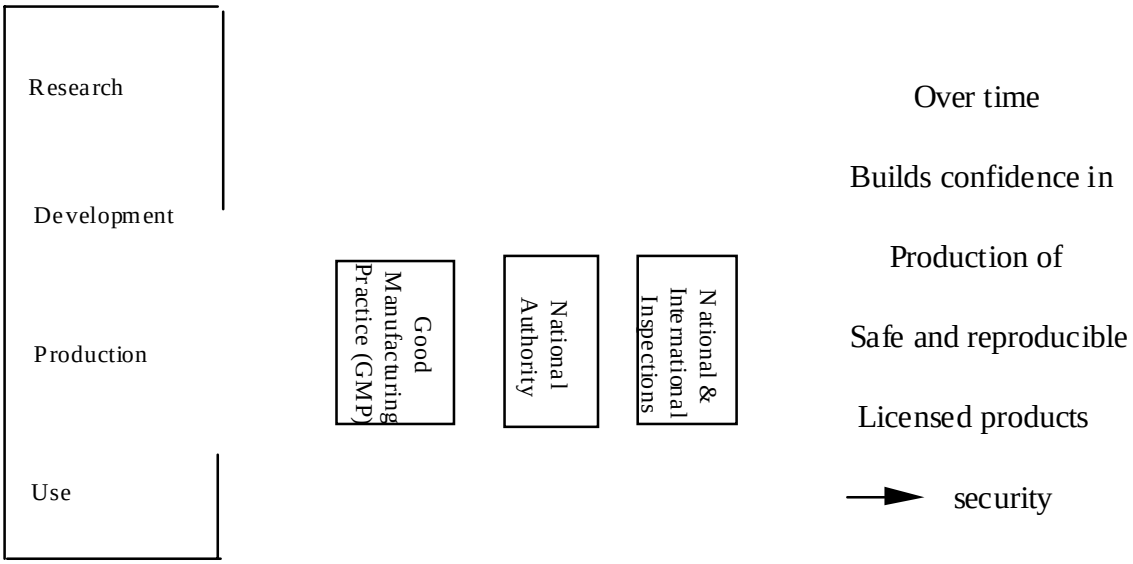
Concerns & Fears

→ Insecurity

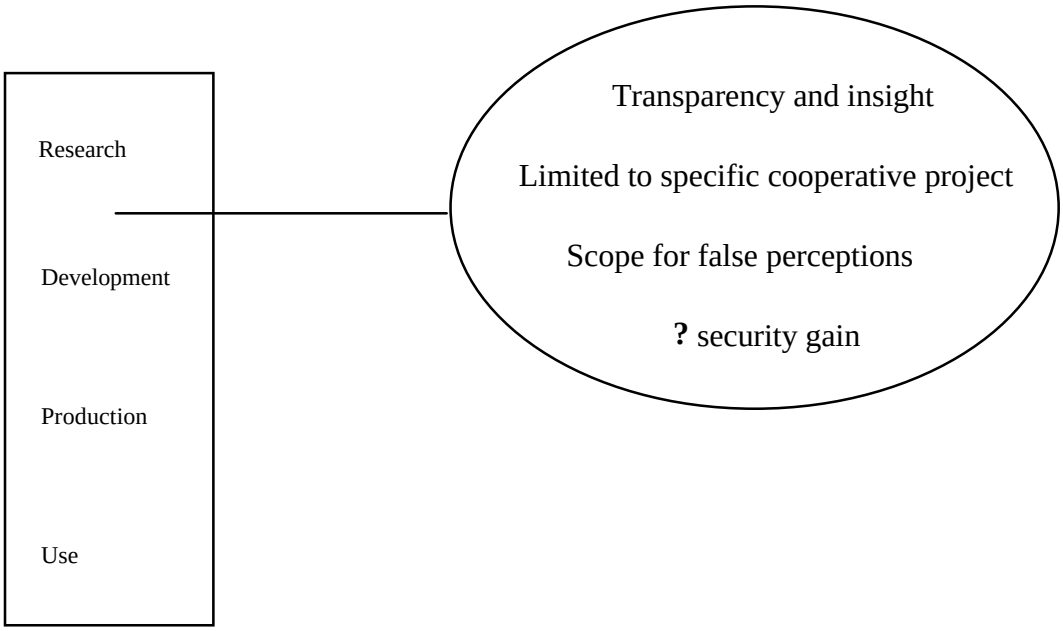
55. The objective was therefore to obtain transparency. The approaches to improved **international biosafety standards** provided a means of improving transparency in every aspect -- research, development, production and use -- of microbiology and biotechnology:



56. In a similar way, the move to **internationally harmonized and inspected standards of GMP** also provided transparency although in the more limited area of production:



57. In contrast, using the same simplistic imagery, **individual international collaboration projects** bring limited benefits:



58. Taking such considerations into mind, it was suggested that a pragmatic approach could usefully be adopted. Consideration of the real world situation for the OPCW and that is probable for the future Protocol Organization shows that:

			International Cooperation and Assistance			
Organization	Total Staff	Total Budget	ICA Staff	% of total	ICA Budget	% of total
OPCW	~ 500	~ US $ 65 M	15	3	US $3 M	5
Protocol Organization	~ 200	~ US $ 30 M	20	10	US $3 M	10

Consequently, assuming a US $3M budget in the future BTWC Protocol Organization for international cooperation and assistance, what are the priorities and what criteria might be used in selecting cooperation projects.

59. It was suggested that the criteria might be:

1. Broad applicability to microbiological and biotechnological activities

2. Direct improvement of transparency

3. Are independent competent authorities involved?

4. Are there independent national inspections?

5. Does the project contribute to an overall framework which builds confidence and hence enhances security?

60. It was important in considering international cooperation under the future Protocol to remember that:

1. The BTWC Protocol is not unique

2. There are other highly relevant international instruments:

-- Convention on Biological Diversity, Biosafety Protocol
-- Good Manufacturing Practice
-- Regional Directives

3. There are significant benefits from validated (inspected) regulations.

61. The priorities for international cooperation under the future Protocol might be:

1. Implement Protocol -- this is an essential prerequisite.

2. Assist States Parties in assessing needs for national infrastructure

>> benefits for safety, health and prosperity

which result in security

3. Assess the needs **in the round**

biosafety, GMP, and BTWC Protocol

4. Focus on training & maintaining skills

-- building capacity
-- recognising national benefits
-- public information programme

5. Data bases and clearing house mechanism focussed on relevance to the BTWC and its Protocol with links to reputable data on quality websites.

Overall Conclusions

62. The following overall conclusions emerged from the Piestany NATO workshop on "Maximizing Security Benefits from International Cooperation in Microbiology and Biotechnology" held on 18 - 20 May 2000:

1. There is **already** an immense amount of ongoing international collaboration in the fields of microbiology, biotechnology and biosafety. It was evident that those engaged in such collaboration have a great deal to contribute to building safety, health, prosperity and security around the world although many have individually little awareness of the Biological Weapons Convention or its Protocol. For an effective and enduring strong Protocol regime it will be important to reach out to and engage this community. Such engagement will over time contribute directly to greater understanding between developed and developing countries and the easing of tension between these countries as global safety, health, prosperity and security increase.

2. It was evident that there are major initiatives to improve biosafety standards around the world involving the building nationally in each country of the necessary infrastructure for a competent national authority and inspectorate. There is a very well coordinated initiative to do this within the preaccession countries to the European Community. The Biosafety Protocol could provide a similar encouragement to countries around the world in Africa, Latin America and the Caribbean, and Asia. Improved biosafety standards also bring benefits regionally and internationally as neither pathogens nor GMOs recognise boundaries.

3. Likewise, the companies engaged around the world in production of pharmaceutical and biological products are introducing GMP to internationally validated and inspected standards so as to manufacture licensed products which can be sold on the global market. With the expiry of patents, there is a particular opportunity for companies in the developing world who have lower production costs to make bigger profits provided that their production is to internationally inspected GMP standards.

4. The establishment of national infrastructures with competent national authorities and inspectorates in both the areas of biosafety and GMP directly contribute to the improved transparency and the building of national public confidence in the countries concerned which lead to international safety and security.

5. These ongoing initiatives -- into biosafety standards and into Good Manufacturing Practice requiring the establishment of competent national authorities and inspectorates -- directly contribute to increased transparency and thus to building safety, health, prosperity and security around the world. These developments are directly relevant to the Protocol regime to strengthen the BTWC as over time they contribute directly to achieving greater understanding between developed and developing countries and to the easing of tensions as global safety, health, prosperity and security increase bringing benefits to all.

6. As the future Protocol organization is expected to have an overall strength of some 200 staff and an annual budget of around US $30M (less than half the annual budget of the Organization for the Prohibition of Chemical Weapons), it is unrealistic to expect a budget in the Protocol organization for international cooperation of more than a few million US $. Consequently, the organization will need to evaluate the various alternatives for international collaboration so as to focus on those for which the Protocol organization is best fitted to do and which will benefit the States Parties to the Protocol.

7. The international collaboration priorities for the future Protocol organisation are:

i. Implementation of the Protocol

ii. Assist States Parties in assessing their national needs for infrastructure in their country to promote safety, health and prosperity which will bring security.

iii. Assess these national needs **in the round** -- considering biosafety, GMP and the BTWC Protocol.

iv. Focus on training and maintaining skills **within** States Parties so as to:

- build capacity and capability
- enable States Parties to obtain and recognise tangible national benefits
- develop a public awareness programme to develop popular support

v. Develop a web based electronic data-base and clearing house mechanism with "route-map" links to other reputable quality websites to enable States Parties to find good quality data.