

**MEETING OF THE STATES PARTIES TO THE
CONVENTION ON THE PROHIBITION OF
THE DEVELOPMENT, PRODUCTION AND
STOCKPILING OF BACTERIOLOGICAL
(BIOLOGICAL) AND TOXIN WEAPONS AND
ON THEIR DESTRUCTION**

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ARABIC/ENGLISH/SPANISH
ONLY

First Meeting
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Meeting of Experts
Geneva, 18 – 29 August 2003

REPORT OF THE MEETING OF EXPERTS

(Part II)

Annex II

STATEMENTS, PRESENTATIONS AND CONTRIBUTIONS MADE
AVAILABLE TO THE CHAIRMAN

*Note from the Secretariat: the statements, presentations and contributions included in this part of the report are presented in the languages of submission. In cases where the language of submission is not English, the text as submitted is followed by an **informal** transcript of the English interpretation, made from the tape recording of the meeting. These transcripts are **not** an official record, and are provided solely as a convenience for delegations. They may differ from the texts submitted. Statements, presentations and contributions which were submitted as working papers are not included in this Annex; please refer to Annex I for the list of working papers.*

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Monday 18 August 2003

China

The security challenges faced by the international community have been pluralized whereas uncertainties for world security are on the rise. Non-traditional security threats, such as terrorism, proliferation of weapons of mass destruction, transnational crimes, are intertwined with traditional ones. The deepening of mutual-dependency between States in terms of security requests a new security concept featured by mutual trust, mutual benefit, equality and coordination. The system of arms control and non-proliferation regimes established over the years have played an important and positive role in maintaining the international security and stability. It is imperative to keep and improve this system under the present situation, bearing both practical and far-reaching significance in effectively tackling all kinds of challenges.

As part and parcel of international arms control system and global collective security architecture centered on the United Nations, the Biological Weapons Convention has always played an important role in the comprehensive prohibition, thorough destruction and non-proliferation of biological weapons. Since the termination of the seven-years' negotiation of a Protocol to the Convention, the multilateral process of strengthening the Convention's effectiveness has experienced low tide for a time. With the rapid development of biotechnology and escalation of bio-terrorism threats, it has become all the more imperative and important to discuss, within a multilateral framework, concrete measures to strengthen effectiveness of the Convention.

The convening of the Meeting of Experts is the first substantial effort of the international community in strengthening the Convention after the end of the negotiation of the Protocol. Therefore it is of great significance. "Well begin, half done", China believes that the Meetings of Experts and Annual Meetings of States Parties constitute important fora for states parties to explore effective measures to implement the Convention. Through exchange of views and discussions during the multilateral forum, States parties will formulate or improve their national implementation system, taking into consideration of both their specific national situation and the good experience of others, and hence jointly furthering the effective implementation of the Convention.

National implementation measures are basic requirements and guarantee for the States Parties to fulfil the obligations set forth in the Convention. They are also the concrete manifestation of the States Parties' political commitment. All States Parties are duty-bound to take all necessary measures for preventing and prohibiting the development, production, stockpiling, acquisition and retention of biological weapons. Biosecurity measures play a positive role in the protection against and management on pathogenic microorganisms and toxins, the prevention from infecting the related personnel and leaking of pathogenic microorganisms, and the fight against bio-terrorism. Such measures cannot but form an important part in the implementation of the Convention. States Parties should guarantee, through legal and administrative measures, that pathogenic microorganisms and toxins be used for purposes not prohibited by the Convention rather than for biological weapons or bio-terrorism purposes. At the same time, States Parties should attach great importance to safeguarding public health and safety.

China is a victim of biological weapons. We have all along stood for the comprehensive prohibition and thorough destruction of biological weapons and opposed the proliferation of such weapons. The Chinese government thinks highly of the Convention and fulfils its obligations in

a comprehensive and earnest manner. China promulgated and implemented a series of laws and regulations, strictly implementing the prohibition article of the Convention, administering the transfer, shipment, storage and wrapping of the pathogenic microorganisms and toxins and stipulating in details the concrete implementing measures and punishment of illegal activities. These laws and regulations cover the risk assessment and classification of pathogenic microorganisms, the laboratories criteria, operation guidelines etc., which form a complete biosecurity system. We will, according to the principle of rule by law, continue to enhance the relevant law making, enacting and supervision so as to ensure the strict and effective implementation of the Convention in China.

The complicated and profound changes in the international situation and the fast development of biotechnology bring greater opportunities and challenges for the Convention than ever before. The issue of how to turn challenges into opportunities and hence making all the development of biotechnology contribute to the peace and improvement of mankind should be the common task of all States parties. China believes that States parties will reach common understanding on effective action of strengthening the Convention by continued effort under the multilateral framework. China will make effort with all the other sides to realize this objective.

Brazil

Now that the follow-up mechanism agreed upon at the resumed session of BWC's Fifth Review Conference is starting, I would like to recall the positions of Brazil regarding the implementation of the BWC.

Brazil is willing to examine the subjects approved in the resumed session of the Fifth Review Conference of the States Parties, since the common understanding is that these discussions do not exclude other issues of the BWC.

The preference of certain countries for unilateral or plurilateral action to combat weapons of mass destruction, including biological weapons, cannot obliterate the primacy of the principles and rules of multilateralism on this matter. The lack of multilateral coordination may result in the failure of the regime established by the BWC. Legitimate action in the area of international security must be founded on multilateral agreement.

It is essential that the international community find solutions to combat the threat posed by biological weapons. Effective global biological disarmament, the main objective of the BWC, must be verifiable. It is also necessary to implement a reliable international system on the non-proliferation of biological weapons, without the violation of the States Parties' right to have access to agents and technologies for peaceful uses. Beside many others, these are questions that should be tackled in an integrated manner, so that the gaps in the BWC can be covered. There is no other way for dealing effectively with disarmament and non-proliferation issues concerning biological weapons than the BWC.

Between 1995 and 2001, Brazil actively participated in the negotiations to strengthen the Biological and Toxin Weapons Convention (BWC) with a verification protocol. We understand that combating biological weapons must be undertaken through multilateral initiatives. Since sensitive goods and technologies are disseminated worldwide, the entire international community must discuss and put into force effective and consensus-based rules.

The regime to prevent biological weapons is based on a set of reciprocal obligations negotiated by the States Parties to the BWC. The meeting's "deliverables" should fully take into account that countries signed the BWC as an integrated group of fifteen articles covering the concerns and objectives of States Parties. These include, inter alia, the issues of disarmament and non-proliferation, as well as the need to ensure access to biotechnology for peaceful uses, scientific and technological cooperation, and humanitarian assistance.

Unfortunately, of late there has been selectiveness in the consideration of the BWC. In 2002, the resumed session of the Fifth Review Conference of the States Parties to the BWC approved a working program for meetings to be held between 2003 and 2005 in which only a limited number of subjects were included, based on Article IV of the Convention. Nevertheless, Article IV results from Articles I, II, III and X; these are inextricably linked and cannot be examined separately. We particularly regret that important issues such as cooperation in the field of peaceful biological activities (Article X) have been set aside.

Although the BWC lacks verification mechanisms, certain international organisms should not be used to investigate the suspicion of use of biological weapons. It stands to reason that Brazil supports the strengthening of the above-mentioned organizations, but it considers that this must be done according to their respective core mandates, lest their effectiveness and legitimacy in achieving their fundamental missions be compromised.

At the international level, discussions on mechanisms should include the need to establish a common mechanism to oversee the implementation of national measures, and to assist in resolving ambiguities and to promote international collaboration in cases of suspicion of unlawful activities, under the terms of the Convention.

The association of the subjects "biotechnology" and "weapons" has no scientific basis and may cause undesirable consequences for developing countries. We reject the idea of inhibiting the application of biological processes in the development of materials and substances for industrial, medical and pharmaceutical uses alleging possible "harmful use" of technology to produce weapons.

The Brazilian views on the way forward have been consolidated in working paper 20.

As in past BWC meetings, the Brazilian delegation will participate in the deliberations of this Meeting actively and constructively.

China

Statement on National Implementation Measures: National Legislation Status

Chinese legislation with regard to the implementation of the prohibition set forth in the Biological Weapons Convention is as follows:

According to China's legal system and legal practice, once an international treaty entered into by China has been ratified, it will become legally effective in China.

In order to further implement comprehensively the obligations of the Convention, China has promulgated and put into practice a series of laws and regulations. With regard to criminal legislation, China has promulgated the Criminal Law and its Third Revision. In civil legislation, the State Council has promulgated administrative regulations such as the Regulations of the People's Republic of China on Export Control of Dual-Use Biological Agents and Related Equipment and Technologies. There are also ministerial rules and regulations, such as the Administrative Measures for the Registration of Exporters of Sensitive Items and Technologies as promulgated by the former Ministry of Foreign Trade and Economic Cooperation.

These laws and regulations are mutually complementary. Jointly, they form a multilayer, comprehensive legal system for implementing the Convention. China has already taken, and will continue to take, all kinds of measures to ensure the implementation of all the laws and regulations in a strict and effective manner, with an aim to implement fully the obligations of the Convention. China has already submitted to the meeting a working paper named "National Implementation Measures and Biosecurity and Oversight Mechanism: Practice and Proposals", covering the related practice and position of China, which will be distributed soon.

United States

Overview of National Implementation Measures in the United States

Scope of U.S. National Implementation Measures

- Penal legislation: prohibited activities
- Jurisdictional scope
- Penalties
- Seizure and destruction authority
- Export controls
- Security measures

Nature of the U.S. Legal Regime

- The United States employs a variety of domestic measures to implement obligations under the BWC, and to deter and prevent illicit activity involving biological agents and toxins.
- Core penal provisions are adopted as statutes, enacted by the U.S. Congress, and enforced by the courts. Important legal measures are also issued as regulations by the Executive Branch.
- Policy guidance to Executive Branch agencies may be provided by Presidential Executive Order.

Penal Legislation: Prohibited Activities

- The U.S. has enacted two key statutes in this area: one specifically addresses biological weapons, the other covers WMD in general.

- The biological weapons-specific statute closely tracks the prohibitions under the BWC. This law makes it a crime to knowingly develop, produce, stockpile, transfer, acquire, retain or possess a biological agent, toxin, or delivery system for use as a weapon. [18 USC 175(a)]
- The law requires a showing of criminal intent (i.e., that the purpose is “for use as a weapon”). Intent may be inferred from the circumstances.
- Another provision prohibits possession of an agent or toxin of a type or in a quantity not justified for peaceful purposes. This provision requires no additional proof of intent. [18 USC 175(b)]
- U.S. law prohibits “conspiracy” and “attempt” to violate these prohibitions [18 USC 175(a)], as well as the “harboring” of violators [18 USC 2339].
- Penal provisions also cover violation of registration requirements and transfer restrictions concerning biological agents and toxins. [18 USC 175b]
- The general WMD statute makes it a crime to use, or to threaten, attempt or conspire to use, a WMD, including a biological weapon. [18 USC 2332a]

Jurisdictional Scope

- U.S. legislation provides criminal jurisdiction over all activities on U.S. territory.
- The legislation also extends jurisdiction based on “active” and “passive” nationality (crimes by or against U.S. nationals abroad). [18 USC 175, 2332a]

Penalties

- Wide range of criminal penalties (fine or imprisonment), depending on nature and severity of the offense.
- In grave cases, conviction may result in life imprisonment, or, if the death of a victim results, capital punishment. [18 USC 175, 2332a]

Seizure And Destruction Authority

- U.S. law authorizes law enforcement authorities to act promptly to halt suspect activity.
- Authorities may seize biological agents, toxins and delivery systems pursuant to court order, and in an emergency may proceed without a court order. [18 USC 176]
- After appropriate judicial proceedings, the courts may order forfeiture and destruction of the seized items.

Export Controls

- The U.S. controls the export of agents and equipment that are biological weapons sensitive.

- These measures reflect the non-proliferation obligations under the BWC.
- Export of “dual use” items are controlled under detailed legislation and regulations. [22 USC 5603; 22 USC 2751 et seq; 22 CFR 120-130; 50 USC App 2401 et seq; 15 CFR 730-774]

Biosecurity Measures

- U.S. law controls access to dangerous pathogens and toxins (defined as “select agents and toxins” in U.S. law).
- All facilities possessing select agents and toxins must register with and be approved by the U.S. government. [42 USC 262a; 7 USC 8401]
- The government maintains a database with the names and locations of all registered facilities, including a record of the agents and toxins held by each.
- Mandatory security requirements imposed on approved facilities, including risk assessment, physical security measures, access control restrictions and secure transport regulations.
- Mandatory background checks for facility and transport personnel.
- Designation of national oversight bodies – Department of Health and Human Services for dangerous human pathogens and toxins; U.S. Department of Agriculture for animal and plant pathogens and toxins.

Republic of Korea

Let me briefly explain our national measures taken or to be taken to implement the provisions of the BTWC. Although our national measures are neither perfect nor exhaustive, we hope that our national experience can provide useful guidance on our deliberations on the subject.

The Republic of Korea stands for the comprehensive prohibition of biological and toxin weapons and opposes their proliferation. For this purpose, the Republic of Korea has faithfully implemented its obligations and duties under the Convention since its accession to it in 1987. The Convention has been incorporated into our domestic legal system in accordance with our legal system. As such, the Convention is regarded as part of our legal system. However, as we will set out in our input paper entitled “National Measures or Legislation to Implement the BTWC: A Conceptual Analysis”, as contained in wp16, we need some implementing legislation or measures, since the Convention lacks specific provisions for domestic enforcement.

The Republic of Korea has not enacted a separate penal legislation in order to implement the Convention. At present, the activities prohibited in Article I and IV of the Convention can be punished by invoking various types of crimes set out in our criminal code such as preparations for homicide, conspiracy with intention to murder etc. This is not sufficient, however, for fulfilling the obligations under the Convention.

In order to fill the void resulting therefrom, my Government is in the process of enacting an additional domestic legislation. This legislation is the Act on the Punishment of Terrorist

Bombings and the Financing of Terrorism, which constitutes one of the comprehensive measures to cope with new threats posed by terrorism. The Act provides for an aggravated punishment for using, attempting to, or preparing to use biological agents or toxins for purposes other than peaceful ones. It will also apply to the acts committed against Korean nationals in a foreign country as well as those committed by Korean nationals in a foreign country. This Act, which is expected to be adopted by the end of this year, will contribute to the more effective implementation of the Convention.

In view of the recent acts of bio-terrorism, the importance of full adherence to Article III of the Convention has taken on greater practical meaning. In accordance with this Article and relevant domestic law, the Republic of Korea has never tried to transfer nor have ever made it possible to transfer any agents, toxins, weapons, equipment, or means of delivery specified in Article I of the Convention, to any recipient. In addition to such a policy, the Republic of Korea has kept a strengthened export control system.

The Foreign Trade Act provides the legal grounds for the Public Notice on Export and Import of Strategic Goods, which maintains controlled lists of materials, agents, equipment and technologies and provides for detailed procedures for export. The Act also has a provision that enables the Government to inspect any deceitful or unlawful export as well as a penal provision. The implementation decree of the Act provides for export permission for strategic goods, the issuance of import certification, and sanction for persons disqualified for transaction.

In an effort to effectively prevent the proliferation of weapons of mass destruction including biological weapons and to fight against terrorism, the Republic of Korea introduced the catch-all system into its domestic legal framework in January 2003 and has been implementing it accordingly. Article 81 to 85 of the Public Notice regulates the non-listed dual-use goods that can be used to develop, produce, use or stockpile weapons of mass destruction and their delivery systems. It stipulates that the authorizing agency may pose a restriction on the issuing of an export license to a person who intends to export non-listed dual-use goods to the country which is developing or is suspected of developing WMD. A person who intends to export the above mentioned dual-use goods should apply for an export license when he or she received information that the export goods are used or can be used for WMD, when he or she knows that an importer is engaged in WMD activities or when the authorizing agency requests the exporter to apply for an export license.

In relation to the security and safety of biological agents and toxins, which will be discussed in more depth next week, the Republic of Korea has enacted diverse provisions in many areas. Although these provisions may not have been adopted directly for the implementation of the Convention, they provide mechanisms and means for strengthening and implementing the Convention in one way or another. To name a few among these, we have "The Prevention of Contagious Disease Act", "Pharmaceutical Affairs Act", "Act on the Prevention of Livestock Disease Act", "Plant Protection Act", "Biotechnology Support Act", "Quarantine Act", etc.

We believe that implementing effective domestic measures is a key to fulfilling the objectives of the Convention. The Government of the Republic of Korea will keep reviewing the efficacy and effectiveness of our domestic system in implementing the Convention and take additional measures, if necessary.

Japan

Japan's Legal Regulatory & Administrative

Civil Legislation

When Japan ratified the BWC in 1982, the Japanese Diet enacted “the Law on Implementing the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction” (the BWC implementing Law). The purpose of the Law was, as articulated in its Article 1, to criminalize and penalize such acts as prohibited by the BWC and thereby to fulfill the requirements of the Convention.

Penalties inflicted against the violation of the prohibition in the BWC are described as follows. Either imprisonment with labor of one to fifteen years or a fine of up to five million yen (approx. 42,000 USD) shall be inflicted for those who produce or develop biological and toxin weapons. Either imprisonment with labor of a maximum of ten years or a fine of up to three million yen (approx. 25,000 USD) for those who retain, transfer, or acquire these weapons. Either imprisonment with labor of an indefinite period, that of more than two years, or a fine of up to ten million yen (approx. 84,000 USD) for those who use these weapons. In addition to these penalties, other charges and punishments will also be imposed in accordance with the Criminal Law and other relevant laws and regulations.

The BWC Implementing Law describes the developing, producing, retaining and acquiring the biological agents and toxins allowed only for peaceful purposes and at the same time empowers relevant Ministers in the government to order persons to make compulsory reports regarding their activities to these Ministers to the extent necessary for preventing the activities for purposes other than peaceful ones. In order to define the Ministers who have such authority, the Cabinet Order has been enacted in which at the same time the responsible Ministers for national publicity about the BWC and the BWC implementing Law.

India

India had hoped that the Protocol which we negotiated over so many years, and was so tantalizingly close to adoption could have been adopted. Had that been the case, all the States that ratified such a Protocol would have naturally followed it through with necessary national legislation and procedures to bring them in line to implement the provisions set forth in the Convention, as well as establish and maintain the security and oversight of pathogenic microorganisms and toxins. The fact that the Protocol could not be adopted has in fact been a setback to the national implementation measures, which we are going to discuss at great length and great detail over these two weeks.

India, however, welcomes this process, as it is anchored in the multilateral process, necessary for addressing such important issues that affect the security of all nations. It is in this spirit that we look forward to participating in the deliberations of this Expert Meeting which we hope, will have a positive and fruitful outcome.

The Government of India, taking into account the potential risks to human life and environment, has adopted regulatory mechanisms for the production, import, export, use, research of microorganisms, genetically modified organisms and toxins. The Prevention of Terrorism Act of March 28, 2002 has provision for the prevention of, and for dealing with terrorist activities, including those involving biological substances of a hazardous nature. In the case of death of any person resulting from such an act the person responsible would be punishable with death or imprisonment for life. In a situation where such an act is perpetrated even without resulting in the death of person, the person responsible would be punishable with imprisonment for a term which shall not be less than five years but which may extend to imprisonment for life.

The Foreign Trade (Development and Regulation) Act of 1992 exercises control over Special Chemicals, Organisms, Materials, Equipment and Technologies (SCOMET) items including in biological and biotechnological applications. Export or attempt to export in violation of any of the conditions of license to export shall, *inter alia*, invite criminal prosecution under the Customs Act, 1962.

In 1986, the Government enacted binding rules for the manufacture/ use/import/export and storage of hazardous microorganisms/genetically engineered organisms or cells which cover a broad range of activities including sale, offer for sale, storage for the purpose of sale, offers and any kind of handing over with or without a consideration of such materials. Failure to comply with or contravention of any of the provisions of these rules attract penal provisions of the Environmental (Protection) Act of 1986.

The Environmental (Protection) Act of 1986 empowers the Government of India to take all such measures as it deems necessary, including laying down procedures and safeguards for the handling of hazardous substances. The Act includes penal provisions for imprisonment for a term which may extend to seven years.

It may also be mentioned that the Epidemic Diseases Act of 1896 provides the Government with power to take special measures and prescribe regulations relating to dangerous epidemic diseases.

It is clear that India has a long history of adopting legislative measures which have been consistently updated and strengthened taking into account the developments in technology and the potential for misuse. Several legislative and regulatory measures already exist in India to deal with in a comprehensive manner, the issues we are addressing at this Expert Meeting. The penal provisions are also severe enough, by all standards, to address the grave nature of the issue. The experts in my delegation will be happy to share details of the legislation and regulatory mechanisms as well as our practical experience in implementing them. We also look forward to learning from the experiences of other countries and consider positively the ideas that distinguished experts belonging to numerous delegations will have to offer at this Meeting.

Cuba

Mi país concede gran importancia a la discusión de este tema sobre las medidas legislativas nacionales para aplicar las disposiciones contenidas en la Convención, incluida la promulgación penal, que brinda la oportunidad de exponer nuestras experiencias nacionales en la materia.

En primer lugar, debo anunciar que en breve entregaremos a la Secretaría dos documentos de trabajo de Cuba sobre cada uno de los temas que estarán bajo discusión en esta reunión, siguiendo el mandato acordado en la 5ta Conferencia de Examen de los Estados Partes en la Convención.

Lamentablemente ambos documentos serán presentados en español, aunque hacemos todos los esfuerzos para entregar también versiones en inglés a la Secretaría para que sean distribuidas antes de que finalice esta reunión de expertos.

Asimismo, entregaremos adicionalmente dos CD-ROMs que contienen bases de datos con los detalles de la legislación cubana en materia de bioseguridad y relacionada con la aplicación de la Convención de Armas Biológicas. Nos es imposible facilitar copias para cada una de las delegaciones presentes pero la información puede ser consultada en la Secretaría y, si es posible reproducida para la entrega de copias a las delegaciones interesadas.

Cuba ha logrado conformar un sistema integral de medidas, incluida la promulgación de legislación penal, dirigidas a garantizar la plena aplicación de todas las disposiciones contenidas en la Convención.

Los antecedentes más remotos se remontan a 1989 cuando existía en mi país una Comisión de Seguridad Biológica, dirigida por la Academia de Ciencias de Cuba

En 1994, con la promulgación de la Resolución No.1 de la Comisión Nacional para la Protección del Medio Ambiente y Uso Racional de los Recursos Naturales (COMARNA), *se* comenzó a organizar la bioseguridad con carácter institucional por primera vez en el país.

En 1996 por la Resolución No. 67 del Ministerio de Ciencia, Tecnología y Medio Ambiente (CITMA) se crea el Centro Nacional de Seguridad Biológica (CSB), con el fin de organizar, dirigir, implementar, supervisar y controlar el sistema nacional de seguridad biológica, y organizar, dirigir y controlar las medidas encaminadas a dar cumplimiento a las obligaciones contraídas por la República de Cuba como parte de instrumentos jurídicos internacionales relacionados con esta materia, incluida la Convención de Armas Biológicas y Toxínicas.

En 1999 se adopta el Decreto Ley 190 de la Seguridad Biológica, como base del sistema legal para la bioseguridad en Cuba. Este Decreto Ley establece los preceptos que regulan el uso de agentes biológicos, organismos y fragmentos de éstos con información genética en el país, así como las actividades encaminadas a garantizar el cumplimiento de los compromisos internacionales asumidos por la Republica de Cuba en esta materia.

Con fecha 9 de abril del 2003 el Comité Ejecutivo del Consejo de Ministros adopta el Acuerdo No.4728 designando al CITMA como autoridad nacional en los temas referidos a la Convención de Armas Biológicas y Toxínicas (CABT).

Actualmente se encuentra en fase de aprobación por el CITMA, el Reglamento para la Contabilidad y Control de materiales biológicos, equipos y tecnología aplicada a éstos. El objetivo de este documento es establecer el Sistema Nacional de Contabilidad y Control de dichos componentes en virtud de lo establecido en la Convención de Armas Biológicas y Toxínicas. En el Reglamento se recoge la base del Sistema, los elementos que lo integran, tales como, las declaraciones que deben hacer las instalaciones que realicen actividades de interés para la

Convención de Armas Biológicas y Toxínicas (CABT), así como los inventarios, registros e informes sobre agentes, equipos y tecnologías que deben ser enviados al Centro Nacional de Seguridad Biológica.

Cabe destacar que en el Reglamento también se incluyen, otorgándole carácter vinculante, los formularios para el fomento de la confianza adoptados por la Tercera Conferencia de Examen de la Convención sobre Armas Biológicas y Toxínicas.

Ello quiere decir que, con la adopción del nuevo Reglamento, todas las instalaciones existentes en Cuba que realicen actividades de interés para la citada Convención, tendrán la obligación jurídica de enviar cada año al Centro Nacional de Seguridad Biológica dichos formularios debidamente completados, los que después de ser procesados, formarán parte de la información que anualmente presenta Cuba a las Naciones Unidas en virtud de las medidas de fomento de la confianza actualmente en vigor.

Como parte de la implementación de medidas nacionales de carácter penal relacionadas con el cumplimiento de las prohibiciones de la Convención sobre Armas Biológicas y Toxínicas, en diciembre del 2001 se promulga la Ley No. 93 Ley contra actos de terrorismo.

Esta Ley da especial atención a las distintas formas de realización de actividades terroristas y dentro de ella a las relacionadas con agentes químicos o biológicos, que en los últimos tiempos son objeto de especial interés por parte de la comunidad internacional.

Se da carácter complementario en esta Ley a la Parte General del Código Penal y de la Ley de los Delitos Militares, evitando repetir numerosas disposiciones, y a las leyes de Procedimiento Penal y Procesal Penal Militar, para dado el carácter especial de la presente legislación, reafirmar con claridad las normas procesales que rigen en su aplicación.

Por último deseo destacar la disposición de Cuba a compartir sus experiencias nacionales con aquellos Estados Partes que así se lo soliciten y de ese modo contribuir al desarrollo de las capacidades legales nacionales para una cabal aplicación de la Convención.

(informal transcript of the English interpretation)

My delegation would like, on behalf of my country, to take this opportunity under agenda item 5 to share with States Parties here Cuba's experience with respect to the implementation of the Convention on Biological Weapons through our national legislative process.

Before giving a general description of our legislative system, however, I would like to say that shortly we shall deliver to the Secretariat two working papers where we describe first of all the entire Cuban legislative system and the second with respect to the matter we will be considering in the second week, national measures for implementation of the Convention. However, we are talking about legislative measures at this point and I will therefore just refer to one of those.

Regrettably, the document we will be handing the Secretariat shortly is in Spanish and I know that Spanish is not an impediment here in Geneva given the sheer number of colleagues here who have surprised me through their use of Spanish, but nevertheless we are doing our utmost to be able to translate into English both of these documents and we trust that they will be ready before the work of this Group of Experts comes to an end.

And now I will refer to the general description of one of these documents and in so doing I will be referring to the national legislation to be found in Cuba to give effect to the Convention on Biological Weapons. Cuba has developed a comprehensive system, an array of measures including promulgation of peaceful legislation to ensure full implementation by my country of all the provisions to be found in the Convention. The earliest precedent to this dates back to 1989 when there was a Biological Security Commission under the biological front shared by the Academy of Sciences. Subsequently in 1994, with the enactment of Resolution 1 of the National Commission for the Protection of the Environment and rational use of natural resources, work began on organising bio-security measures at the institution throughout the country for the first time.

In 1996, pursuant to Resolution 67 of the Ministry of Science, Technology and the Environment, a National Centre for Biological Safety was established with a view to organising, addressing, implementing, monitoring and controlling a national biological safety system and organising, directing and controlling measures to give effect to Cuba's obligations as a party to legal instruments in this field, including the Convention on Biological and Toxin Weapons.

In 1999 Decree Law 190 on Biological Safety was adopted as the legal underpinnings for biosecurity, biosafety in Cuba. That decree law establishes the principles governing the use of biological agents, organisms and related particles for purposes in the country as well as with a view to ensuring fulfilment of international undertakings assumed by the Republic of Cuba in this field.

More recently on 9 April 2003, the Executive Committee of the Council of Ministers adopted agreement 4728 designating the Ministry of Sciences, Technology and the Environment as the national authority in matters relating to the Convention on Biological and Toxin Weapons. Today the Ministry is in the process of approving regulations for accounting and monitoring of biological materials, equipment and technology. The objective of the document is to establish a national system for accounting and control for these components pursuant to the provisions of the Convention on Biological and Toxin Weapons. The regulations set out the basis of this system and components, such as the declarations to be made, the agents to conduct related activities under the Convention on Biological and Toxin Weapons as well as the inventories, registers and reports on agents, equipment and technology to be forwarded to the national Centre of Biological Safety in Cuba.

We would note that under the regulations you will also find the binding formulas for confidence-building adopted by the Third Review Conference of the BWC. This means that with the adoption of the new regulations all facilities existing in Cuba, which carry out related activities connected with the Convention will have a legal obligation to send on a yearly basis to the National Centre for Biological Safety all the forms duly filled in. These will then become part of the information presented annually by Cuba to the United Nations under the arrangements for confidence-building measures.

As part of the implementation of national measures of a penal nature related to the prohibitions under the Convention, in December 2001 the Cuban Parliament enacted Law 93, the Counter-Terrorism Act. This law pays particular attention to the various ways in which terrorist activities may be carried out and in particular as related to chemical or biological weapons, which in recent times have become a matter of particular concern for the international community.

In this legislation we have the general part of the code and military offences with a view to avoiding repetition of many legal provisions in view of the special nature of this legislation, clearly reaffirming the procedural norms, which apply.

And lastly I would like to re-emphasize my country's willingness to share our experiences which are set out in detail in the documents we will be shortly presenting to the Secretariat. As I say, we will be happy to share our experience with other States Parties which so request, with a view to contributing to all the capacity of such interested States. Truly we will be providing the Secretariat with a CD-ROM containing a database setting out the various details of Cuba's national legislation with respect to implementation of the Convention on Biological Weapons. Unfortunately we do not have a copy for each and every delegation at present here but we do think that anyone concerned would be able to contact the Secretariat and would be able to consult the CD and perhaps it would be possible to make a copy. Indeed you will find there all the details on Cuba's legislation, which is set out to provide information concerning how we are implementing the Convention in Cuba.

United States

Possession, Use, and Transfer of Select Agents and Toxins

The Law

Public Health Security and Bioterrorism Preparedness and Response Act of 2002

- Signed by President Bush on June 12, 2002
- Secretary of Health and Human Services
- Secretary of Agriculture
- Attorney General of the United States

HHS and USDA

- Establish a list of biological agents and toxins that have the potential to pose a severe threat to:
 - HHS: public health and safety
 - USDA: animal and plant health, or to animal and plant products
- Identification and registration of those that possess, use, or transfer select agents and toxins
- Establish safety and security procedures
- Without limiting availability for research, education, and other legitimate purposes

The Attorney General of the United States

Use criminal, immigration, national security, and other electronic databases to determine whether an entity or an individual is:

- A restricted person
- Reasonably suspected of
 - Committing an act of terrorism (18 USC 2332b)

- Involvement with a terrorist organization
- Being an agent of a foreign power (50 USC 1801)

Restricted Persons

A restricted person (18 USC 175b)

- Convicted or under indictment for a felony
- A fugitive from justice
- An unlawful user of any controlled substance (21 USC 802)
- An alien illegally or unlawfully in the United States
- An individual who is mentally defective or committed to a mental institution
- An alien from a country supporting terrorism
- Dishonorably discharged from U.S. military

The Regulations

- Published jointly by HHS and USDA: December 13, 2002
 - 42 CFR Part 73 (Human health)
 - 7 CFR Part 331 (Plant health)
 - 9 CFR Part 121 (Animal health)
- Creation of Select Agent and Toxin Lists
 - HHS only
 - USDA only (Plants)
 - USDA only (Animals)
 - Overlap

Phase-in of New Requirements

- March 12, 2003: Registration applications
- March 12, 2003: Transfer Requirements
- April 12, 2003: Security Risk Assessments
- Sept. 12, 2003: Security Plan Implementation
- Nov. 12, 2003: Full Compliance

Selection Criteria for Select Biological Agents and Toxins

- Effect on human health
- Effect on animal or plant health
- Effect on marketability of animal or plant products
- Degree of contagiousness
- Methods of transfer
- Availability and effectiveness of pharmacotherapies and immunizations
- Other criteria the Secretary thinks appropriate
 - Toxins: potency and quantity
 - Effect on children

Select Agents and Toxins

| | Overlap | HHS | USDA (P) | USDA(A) |
|----------|---------|-----|----------|---------|
| Viruses | 4 | 9 | 1 | 14 |
| Bacteria | 9 | 3 | 5 | 3 |
| Fungi | 1 | 1 | 4 | |
| Toxins | 5 | 7 | | |
| Other | | | | 1 |

Genetic Elements, RNA, and Recombinant Organisms

- Select agent viral nucleic acids (synthetic or naturally derived, contiguous or fragmented, in host chromosomes or in expression vectors) that can encode infectious and/or replication competent forms of any of the select agent viruses.
- Nucleic acids (synthetic or naturally derived) that encode for the functional form(s) of any of the select toxins if the nucleic acids:
 - Are in a vector or host chromosome;
 - Can be expressed in vivo or in vitro; or
 - Are in a vector or host chromosome and can be expressed in vivo or in vitro
- Select agents and toxins that have been genetically modified

Exclusions

- Select agents and toxins in their naturally occurring environment, provided that it has not been intentionally introduced, cultivated, collected, or otherwise extracted from its natural source
- Non-viable select agent organisms or nonfunctional toxins
- May exclude attenuated strains of select agents or toxins upon a determination that they do not pose a severe threat to the public health and safety; or animal health, or to animal products
- Specific de minimus quantities of toxins

Exemptions

- Clinical or Diagnostic Laboratories
 - Agents used only for diagnosis, verification, or proficiency testing (no reference or retention allowed)
 - Transferred or destroyed after identification
 - Notification of federal and state authorities
- Products approved under a Federal Act
- Investigational products (must be requested)
- Public health or agricultural emergency (must be requested)

An Entity Must

- Designate a Responsible Official
- Identify each select agent or toxin it possesses, uses, or transfers
- Identify the individuals it wishes to have access to select agents and toxins
- Receive prior approval of all transfers

An Entity Must also

- Develop and implement safety and security plans
- Maintain inventories and other records
- Conduct safety and security training
- Develop an emergency response plan
- Provide notification of theft, loss, or release of a select agent or toxin

The Government Must Approve

- The Entity
- The Responsible Official
- Individuals who will have access to select agents and toxins
- All transfers

Government Inspections

- Implementation of the safety plan
- Implementation of the security plan
- Emergency response plan
- Training
- Records
- Compliance with all requirements of the rule

Regulation of Research (1)

- An entity may not conduct the following experiments unless approved by the HHS Secretary:
 - Experiments using recombinant DNA that involve the deliberate transfer of a drug resistance trait to select agents that are not known to acquire them naturally, if such acquisition could compromise the use of the drug to control disease agents in humans, veterinary medicine, or agriculture[NIH Guidelines: Major Action, RAC approval]

Regulation of Research (2)

- An entity may not conduct the following experiments unless approved by the HHS Secretary:

- Experiments involving the deliberate formation of recombinant DNA containing genes for the biosynthesis of select toxins lethal to vertebrates at an LD₅₀ < 100 ng/kg weight.

[NIH Guidelines: Require NIH/OBA and IBC approval]

Enforcement

- Civil Money Penalties
 - Up to \$250,000 for an individual per violation
 - Up to \$500,000 for an organization per violation
- Criminal Penalties
 - Imprisonment for up to 5 years, a fine, or both for:
 - Transfer of a select agent or toxin to an unregistered person
 - Possession of a select agent by an unregistered person

INFORMATION

- CDC Select Agent Program:
 - <http://www.cdc.gov/od/sap>
- USDA/APHIS:
 - <http://www.aphis.usda.gov/vs/ncie/bta>

Japan

Development of Japan's Penal Provisions

Due to the fact that the prohibition of use of biological weapons is stipulated in the 1925 Geneva Protocol and not in the BWC, up until two years ago, the use of these weapons was not penalized by the BWC Implementing Law and was considered to be treated as a crime stipulated in the general penal code. For example, murder or insurrection in the Penal Code would be applied to the use of biological weapons according to the situation. The Japanese Diet amended the BWC implementing Law in 2001 when it ratified the International Convention for the Suppression of Terrorist Bombings, and added to the Law an article regarding the prohibition and penalty against the use of the weapons and discharge of biological agents and toxins. Either imprisonment of an indefinite period, that of more than two years, or a fine up to ten million yen for those who use these weapons.

China

Statement on National Implementation Measures: Activities Prohibited by the Convention

In order to implement earnestly the prohibition set forth in article one of the Convention, China has promulgated and put into practice a series of laws and regulations, the major part of which is the Criminal Law and its Third Revision.

It is provided that, any illegal manufacturing, trading in, transporting, storing, using, stealing, snatching or robbing of any toxic substances or infectious pathogens constitutes a crime against public security and shall receive imprisonment of no less than three years and no more than ten years if no serious consequences are caused thereby. A punishment of ten years and above imprisonment, life imprisonment or death may be imposed if serious consequences are caused thereby.

Any using of false toxic substance or infectious pathogens, or fabricating terror news such as biological and chemical threats, or further spreading knowingly fabricated terror news and cause serious social disorder shall receive a punishment of no more than five years imprisonment, detention or be put under surveillance; or receive imprisonment of five years and above if serious consequences are caused thereby.

The said provisions cover Article I of the Convention.

Tuesday 19 August 2003

Ukraine

First of all I would like to draw attention of all participants to the working papers prepared by Ukraine with regard to the topics to be discussed during the two weeks of work of our meeting. It includes 8 working papers, namely:

- 1) Information on criminal responsibility for the bioterrorist activity and activity aimed at developing of weapons of mass destruction;
- 2) General information on sanitary-epidemiological surveillance system in Ukraine and measures were taken to counteract possible bioterrorist activity in the context of events of autumn 2001;
- 3) Procedure to control access and work with biological agents and toxins in Ukraine;
- 4) Classification of human pathogenic microorganisms;
- 5) National measures in Ukraine to control genetic modifications;
- 6) Procedure of export control in Ukraine of goods that could be used in the development of biological weapons;
- 7) Regulatory measures in the sphere of work with the animal pathogenic microorganisms;
- 8) Information on measures were taken by Ukraine to implement the provisions of Cartagena Protocol on Biosafety.

These working papers will be distributed among the delegations through the Secretariat of the Meeting and our experts will be ready to discuss all this issues during the work on appropriate items of the Agenda.

In the context of discussion of item *Prohibition* I would like to comment the first working paper which relates to the information on criminal responsibility for the bioterrorist activity and activity aimed at developing of weapons of mass destruction.

Any development, manufacture, stockpiling or use of biological weapons is the result of decisions and actions of individual persons, whether they be officials, representatives of the companies, weapons experts or terrorists. At the same time the international convention that prohibits this kind of weapons almost does not assume an individual responsibility. Thus the states are put before necessity to bring in its acts the appropriate provisions which would establish the criminal responsibility for the activity aimed at developing of weapons of mass destruction.

In particular the Criminal Code of Ukraine contains 8 articles that to a certain extent refer to the criminal responsibility for the bioterrorist activity and proliferation of weapons of mass destruction: Article 258 ("Act of Terrorism"), Article 261 ("Attacks on the facilities on which there are items that constitute the enhanced danger to the surroundings"), Article 321 ("Illegal production, making, purchasing, transportation, sending, storage for selling purposes, or sale of poisonous and drastic substances"), Article 326 ("Violation of rules related to handling of microbiological or other biological agents or toxins"), Article 333 ("Illegal exportation outside Ukraine of raw material, materials, equipment, technology for creation of weapons as well as military and special enginery"), Article 439 ("Use of weapons of mass destruction"), Article 440 ("Development, production, purchasing, stockpiling, sale or transportation of weapons of mass destruction"), Article 441 ("Ecocide").

Moreover on March 20, 2003 the Law "On Counteraction of Terrorism" was adopted by the Verkhovna Rada (Parliament of Ukraine). The Law was developed with the purpose to create an appropriate legal basis to counteract the terrorism in all its aspects and forms in the context of implementation of the UN Security Council Resolutions of December 19, 2000, №1333 and of September 28, 2001, №1373, realization of the arrangements that were achieved during the Conference on General Counteraction the Terrorism (Warsaw, November 6, 2001) as well as appropriate international conventions ratified by Ukraine.

The principles, terms, organization and coordination mechanisms to counteract the terrorism were determined by the Law. Significant attention was given to the idea to establish specific organization and legal basis in this sphere, as well as to prevention of the phenomenon of terrorism and regulations on realization of antiterrorist activity.

Taking into account active foreign policy of Ukraine and dynamics of rapprochement of positions of the States on interaction in the field of counteraction the terrorism, the Law contains special provisions that regulate the issue of international cooperation in this sphere.

The separate section is devoted to the issues of compensation for the harm, caused in consequence of terrorist act and to the social rehabilitation of the persons suffered because of the terrorism.

In accordance with the Law it is supposed to bring appropriate provisions to the operating legislation aimed at defining of the norms of responsibility for the violation of legislation pertaining to counteraction the terrorism, prevention and timely revealing of intentions of the persons, who plan to commit terrorist acts, inadmission of financing of terrorist activity, establishment of the control and oversight of legality of measures to counteract terrorism.

Republic of Korea

My delegation wishes to introduce Working Paper 16 entitled "National Measures or Legislation to Implement the BTWC: A Conceptual Analysis" as contained in Working Paper 16 is to provide a basis for, and identify the different types of, national legislation for the implementation of the Biological Weapons Convention. It is neither a paper aimed at introducing a solution to a specific problem related to the domestic implementation of the Convention, nor presenting common elements or models for national measures or legislation. It simply intends to capture an overall framework and list some factors that should be kept in mind when we review our existing legislation or consider adopting new measures.

The first part of the paper deals with the basis for national measures or legislation. Here, the paper highlights the relationship between Article I/III on the one hand and Article IV on the other hand. As you may be well aware, any Article of an international agreement, if it is legally binding, needs to be implemented domestically by necessary means by the States Parties. So Articles I and III, as core obligations by the States Parties to the Convention, need to be implemented in good faith. Article IV specifies this somewhat natural principle in a concrete text and thus complements Article I, III and other Articles in the Convention. In a sense, it provides the real basis for national measures or legislation.

Article IV requires each State Party to (quote) "take any necessary measures to prohibit and prevent the development, production, stockpiling, acquisition or retention of the agents, toxins, weapons, equipment and means of delivery specified in Article I of the Convention" (unquote). It may be said, therefore, that the proper interpretation of Article IV is very important for the appropriate domestic implementation of the Convention. The previous Review Conferences developed and extended common understandings on the Articles of the Convention including Article I, III and IV. Although we are at a quite different stage from the previous review mechanisms, we cannot deny or ignore the developments we made during the previous Review Conferences. The most notable things among these developments are specified in the paper.

The second part of the paper tries to categorize different types of national measures or legislation and elicit some factors in each category to be taken into account when reviewing existing or new measures or legislation.

At the outset of the second part, the paper emphasizes the need for implementing legislation even in the case of so-called *monism* countries, because the Convention lacks specific provisions for domestic implementation or enforcement.

There may be many criteria, standards or viewpoints by which national measures or legislation contributing to the implementation of the Convention can be categorized. The paper provides three basic categories according to the nature of those measures or legislation, that is, prohibitions, regulatory measures and guidelines.

Prohibitions refer to the national legislation that orders natural or legal persons within a State Party not to do specific activities and provides for certain penalties against violation. By nature, this kind of legislation is penal law, and need to be passed by the legislative body of a State Party. As you know, some States Parties have enacted a separate legislation to provide for these prohibitions, reflecting the text of the Convention without much change. The paper, however, suggests that there may also be other ways of implementing the obligation to prohibit the activities as stipulated in Article IV of the Convention, that is (i) by determining rightfully that existing laws are sufficient (ii) by amending the existing laws and incorporate into them the requirements of the Convention and (iii) by enacting a more broadly framed legislation.

In relation to the way mentioned in the first point, the paper points out the difficulty of judging whether a State Party's determination is a right one and whether further legislation is really not necessary. It should also be noted, however, that even if a State Party can punish the activities prohibited in the Convention in one way or another by resorting to penal legislation on crimes related to hazardous substances or agents or on crimes of homicide or mayhem, etc., this might not automatically mean that any "necessary" measures to prohibit those specific activities have been taken. Although much depends on the interpretation of the Convention, we may have to enact some legislation to prohibit those activities as such, as stipulated in Article IV of the Convention. Finally, when we discuss the penal provisions implementing the prohibitions as stipulated in Article IV of the Convention, the scope of activities, personnel, and geographic area covered by the legislation or measures should be taken into consideration.

Regulatory measures refer to those legislation or measures that tell or order natural or legal persons to do something in a certain way in relation to security and safety of certain agents, export control or genetic modification. Regulating measures may be either in the form of a law adopted by the legislature or measures or legislation enacted by the executive. Guidelines, on

the other hand, generally just recommend natural or legal persons to do something in a certain way. In most cases, the States Parties may have adopted those measures and guidelines for different reasons from the implementation of the Convention.

While regulatory measures may resort to two kinds of means for their enforcement, that is, administrative acts or penal punishment, it is necessary for the benefit of clearer thinking and analysis to distinguish between these regulatory measures with penal punishment as a means of enforcement and those provisions mentioned above for implementing the prohibitions of the Convention. The former is to tell a person to do something and to punish him or her if he or she does not, and the latter is to tell a person not to do something and to punish him or her if he or she does.

I hope this paper will contribute to our discussions on national implementation measures.

Iran

The substantial approach of the Islamic Republic of Iran towards the Prohibition of Weapons of Mass Destruction (WMD) and the early accession to the fundamental instruments dealing with such terrible weapons is the clear confirmation to our firm intention towards a world free from WMD.

The Islamic Republic of Iran has signed the “Biological and Toxin Weapons Convention” (BTWC) in 1972 and ratified it in 1973, “the Geneva Protocol for the Prohibition of the Use in War of Asphyxiating, Poisonous or Other Gases, and of Bacteriological Methods of Warfare” in 1929, the Basel Convention in 1994.

We are also party to the Convention on Bio-diversity and presented the instrument of ratification in 1996 and also signed Cartagena Protocol on bio-safety to the Convention on Bio-diversity in 2001.

The Islamic Republic of Iran in line with its obligations assumed under the BTWC, has taken necessary measures to protect the health and safety of its people, as well as measures to protect the bio-life of animals and plants.

In accordance with the Iranian judiciary system which specifically stipulated in Article 9 of civil code, any international instrument which has been adopted by the Parliament would be considered as internal and public law. In addition study has been made on a proper guideline for national implementation of the BWC. Furthermore, according to the basic principle of the Islamic Republic of Iran the development, production, stockpiling and use of any kind of WMDs is prohibited.

In this context, the Islamic republic of Iran has taken specific legal and administrative measures on the national level for implementation of the obligation set forth in the Convention as well as rules and regulations for safe handling of biological agents and toxins to be used for peaceful purposes which will be outlined in full detail in format of a National Paper and the Databank.

Being once itself the victim of weapons of mass destruction, namely Chemical Weapons; Iran opposes and condemns any use of such weapons. In this connection, the Islamic Republic of Iran

believes that any use of biological weapons is, a violation of Article I of the Biological Weapons Convention.

The Convention does not, in its present form, explicitly contain prohibition of the use of these horrifying weapons. Moreover, according to the Geneva Protocol of 1925, The "Use "is prohibited, but some States Parties have already made reservation to that effect, that to keep the right of retaliation for any case of use against them. This issue was brought to the attention of the States Parties for the first time, as the result of initiative of the delegation of The Islamic Republic of Iran during the Fourth Review Conference.

Such initiative has yielded results to the extent that some States Parties has already withdrawn their reservations. However, a number of states, including certain advanced states as yet have kept such reservations.

Iran has never developed, produced, stockpiled or otherwise acquired or retained microbial or biological agents, or toxins, whatever their origin or method of production, of type and in quantities that have no justification for prophylactic, protective or other peaceful purposes; weapons, equipment or means of delivery designed to use such agent or toxins for hostile purposes or in armed conflict which prohibited under article I of the Convention.

The Islamic Republic of Iran is of the view that multilateral approach to the issue of disarmament and elimination of all Weapons of Mass Destruction (WMD) is the only effective and meaningful approach. In this context, we regret that one decade of efforts and seven years of intensive negotiations on prohibition of biological weapons for achieving a multilateral legally binding instrument to strengthen the effectiveness of the Convention that is "the BWC Protocol" has faced a total failure.

National measures and mechanisms, exchange of views and experiences among the Sates Parties would be of some benefits; however the selective approach to the Convention and choosing only five items could not fill the existing gap and will not meet our requirements created by the said failure.

Therefore, while participating actively in the present discussions of the Experts Meeting of the States Parties, looking forward to achieve a balanced and meaningful result to strengthen the Convention to be reflected by consensus in the report of the Meeting.

Japan

Direct Implementation (Definitions in Legislation)

The BWC Implementing Law defines "biological agents" as micro-organisms which are capable of causing diseases or bringing death to animals or plants when reproducing in these bodies, or which are capable of producing toxins.

For the definition of legitimate purposes for which developing, producing, retaining, and acquiring the agents and toxins are allowed, the Law uses almost the same phrase as in Article I of the BWC, namely, "for prophylactic, protective or other peaceful purposes".

Concerning the ‘hostile purposes’, the Law does not have a clear definition, however, it describes the “biological and toxin weapons” as “the items to be used as means of use of force and filled with biological weapons or toxins.”

Development, Production, Possession and Use

Concerning the prohibition of “development” and “production” of biological weapons in the BWC, the BWC Implementing Law of Japan comprehensively prohibits “production” of these weapons on penalties. The term “production” here encompasses both “development” and “production” of weapons.

Either imprisonment with labor of one to fifteen years or a fine of up to five million yen (approximately 42,000 USD) shall be inflicted for those who produce or develop biological and toxin weapons.

Concerning the prohibition of “stockpile or otherwise acquire or retain” the biological weapons in the BWC, the BWC Implementing Law of Japan comprehensively prohibits these activities with penalties, using the term “retaining, transfer and acquisition”.

Either imprisonment with labor of a maximum of ten years or a fine of up to three million yen (approximately 25,000 USD) shall be inflicted for those who retain, transfer, or acquire these weapons.

Concerning the prohibition of “use” of biological weapons in the BWC, the BWC Implementing Law prohibits “use” of biological weapons and “discharge” of biological agents. These provisions were not seen in the original BWC Implementing Law when it was adopted but have been added to the Law 2 years ago with Japanese ratification of the International Convention for the Suppression of Terrorist Bombings.

Either imprisonment with labor of an indefinite period, that of more than two years, or a fine of up to ten million yen (approximately 84,000 USD) shall be inflicted for those who use these weapons.

Developing, producing, retaining, and acquiring the agents and toxins are allowed only for peaceful purposes. The BWC Implementing Law empowers relevant Ministers in the government to order persons to make compulsory reports regarding their activities to these Ministers to the extent necessary for preventing the developing, producing, retaining, and acquiring of biological agents and toxins for purposes other than peaceful ones. In cases where persons ordered to make reports fail to do so or make false reports, they shall be punished.

Each Ministry takes necessary measures with its competence, but in case of the incompliance, law enforcement is provided basically only by the Police.

Turkey

Turkey signed the BTWC in 1972 and ratified the instrument two years later (1974). Currently, Turkey does not have a specific legislation on the BTWC, however according to the Article 90 of the Turkish Constitution “international agreements duly put into effect carry the force of law. No

appeal to the Constitutional Court can be made with regard to these agreements, on the ground that they are unconstitutional”. Furthermore, Turkey has three complementary legislations, which have also been included in the compilation.

Briefly, they are:

1. Law No. 3763 On the Control of Private Industrial Enterprises Producing War Weapons, Vehicles, Equipment and Ammunitions, adopted in 1940. This legislation which was amended in 1997 requires that relevant licenses must be issued by the Ministry of National Defense for the export of all weapons and ammunition, except sporting and hunting rifles. It also regulates international trade on chemicals and equipment used to produce chemical agents. The provisions of this law are being implemented by means of a “Notification Regarding the Goods the Export of Which are Prohibited or Subject to License”. This notification is revised each year taking into account the multilateral obligations of Turkey and evolving conditions. Following the annual revision, this notification is also published in the Official Gazette.
2. The other legislation is Export Regime Decree No. 95/7623 adopted in 1995. This legislation enables a centralized monitoring of the export of sensitive goods, technology and dual-use material on the basis of the exporting company, product, quantity and value. It requires from the exporter to obtain the license as well as a registration note and to apply to the customs authorities within 90 days. Article 3a requires all exporters to be a member of an exporter’s Union in order to be able to export any good or material. It also requires the Istanbul Metals and Minerals Exporters’ Union (IMMIB) to register sensitive goods, technology and dual-use material which denote this registration on the customs declaration.
3. The third legislation is entitled Law to fight Terrorism, Act No. 3713, adopted in 1991. This act provides definitions of terrorism and terrorist organizations, outlines provisions for responding to terrorist activities and punishment for such activities regardless of the means to which the terrorists or terrorist originations may have resorted.

In full compliance with the Article I of the BTWC, Turkey has never developed, produced, stockpiled or otherwise acquired or retained microbial or other agents or toxins. As agreed at the Third Review Conference of the States Parties to the Convention, Turkey regularly presents her declarations for the Annual information exchange of States Parties on Confidence-building measures.

China

Statement on National Implementation Measures: Anti-conspiracy legislation

The Criminal Law of China has made specific regulations related to anti-conspiracy as follows:

1. Preparation for a crime refers to the preparation of the instruments or the creation of the conditions for a crime. An offender who prepares for a crime may, in comparison with one who completes the crime, be given a lighter or mitigated punishment or be exempted from punishment.

2. A criminal attempt refers to a case where an offender has already started to commit a crime but is prevented from completing it for reasons independent of his will. An offender who attempts to commit a crime may, in comparison with one who completes the crime, be given a lighter or mitigated punishment.

3. Discontinuation of a crime refers to a case where, in the course of committing a crime, the offender voluntarily discontinues the crime or voluntarily and effectively prevents the consequences of the crime from occurring. An offender who discontinues a crime shall, if no damage is caused, be exempted from punishment or, if any damage is caused, be given a mitigated punishment.

New Zealand

We have several comments to make, some of which will encompass earlier bullet points in the Annotated Agenda.

This morning you posed for discussion the question of direct as opposed to indirect implementation of the Convention. In New Zealand, we have in effect utilised both options. The BWC has been directly implemented through a single Act of Parliament but in the company of four other Disarmament and Arms Control treaties including the NPT. Under this Act it is prohibited to manufacture, station, acquire or possess or have control over any biological weapon in the New Zealand Nuclear Free Zone established in the Statute. The definition of biological weapons is taken directly from the BWC, which is annexed to the Act. Offences under the Act carry a penalty of imprisonment up to 10 years and are therefore extraditable offences under the Extradition Act. I should mention by way of comparison that the Chemical Weapons Convention because of its more comprehensive nature is the subject of its own statute. So in New Zealand, WMD are essentially covered by two statutes. But we have also complemented our implementation of the BWC through a number of other Statutes, which brings me to the first bullet point under our current topic on complementary legislation.

New Zealand's relevant anti-terrorism legislation is found in the Terrorism Suppression Act and the Counter Terrorism Bill. In the context of biological matters, it will be an offence under the latter to contaminate food, crops, water or other products intended for human consumption. Incidentally, a particular concern for New Zealand is the protection of our agriculture sector from biological substances. In this regard, our anti-terrorism legislation specifies that it will be an offence to infect animals with a disease with the intention of causing serious risk to an animal population or major damage to the economy. As for penalties, the Terrorism Suppression Act makes it an offence punishable by up to life imprisonment to set off intentionally an "...explosive or other lethal device..." in a "...relevant place, facility, or system..." with intent to cause death, serious injury or extensive destruction of public property. An "explosive or other lethal device" is broadly defined to include "... biological agents or toxins or similar substances...".

Legislation aimed at protecting the environment provides further preventive measures for the misuse of hazardous substances. The Hazardous Substances and New Organisms Act 1996 addresses the deliberate importation, development, field-testing or release of new organisms including genetically modified organisms. In particular, the Act prohibits the importation,

transshipping or manufacture of hazardous substances or new organisms without the approval of a specially established body, the Environmental Risk Management Authority.

Other sources of complementary legislation are the Health Act 1956, Biosecurity Act 1993, Customs and Excise Act 1996, and the Customs Export Prohibition Order 2002 – all available at www.legislation.govt.nz

Cuba

Tema: Legislación Complementaria. Legislación Antiterrorista

La legislación complementaria tiene un papel muy importante dentro del sistema establecido en Cuba para dar cumplimiento a las prohibiciones establecidas por la Convención de Armas Biológicas y Toxínicas.

En tal sentido, Cuba implementa un conjunto amplio de medidas y regulaciones en las esferas de la salud pública y el manejo de sustancias peligrosas, entre muchas otras. Parte de esas regulaciones se encuentran incluidas en los materiales que la delegación cubana ha hecho llegar a la Secretaría para que pueda ser consultada por todas las delegaciones interesadas.

En esta ocasión quisiera centrar nuestra intervención en la legislación antiterrorista vigente en Cuba, por sus importantes implicaciones en lo referido al cumplimiento de las prohibiciones de la Convención por nuestro país.

En respuesta al llamado del Secretario General de la ONU y como muestra del firme compromiso de Cuba en la lucha contra el terrorismo en todas sus formas y manifestaciones, Cuba procedió a ratificar en un plazo muy breve las 12 Convenciones Internacionales existentes en materia de terrorismo.

Adicionalmente, solo 3 meses después de los terribles acontecimientos ocurridos en Nueva Cork y Washington D.C, en diciembre de 2001, el Parlamento de la República de Cuba adoptó la Ley No.93 contra Actos de Terrorismo”.

Esta Ley da especial atención a las distintas formas de realización de actividades terroristas y dentro de ella a las relacionadas con agentes químicos o biológicos, que en los últimos tiempos son objeto de especial interés por parte de la comunidad internacional.

Esta Ley tiene como objeto prever y sancionar los actos descritos en su articulado que por la forma de ejecución, medios y métodos empleados, evidencian el propósito específico de provocar estados de alarma, temor o terror en la población, por poner en peligro inminente o afectar la vida o la integridad física o mental de las personas, bienes materiales de significativa consideración o importancia, la paz internacional o la seguridad del Estado cubano.

En relación con la Convención de Armas Biológicas y Toxínicas (CABT) esta Ley contiene en su Capítulo I “Actos cometidos con artefacto explosivo o mortífero, agentes químicos o biológicos u otros medios o sustancias”, los delitos siguientes:

Artículo 10. El que, fabrique, facilite, venda, transporte, remita, introduzca en el país o tenga en su poder, en cualquier forma o lugar, armas, municiones o materias, sustancias o instrumentos inflamables, asfixiantes, tóxicos, explosivos plásticos o de cualquier otra clase o naturaleza o agentes químicos o biológicos, o cualquier otro elemento de cuya investigación, diseño o combinación puedan derivarse productos de la naturaleza descrita, o cualquier otra sustancia similar o artefacto explosivo o mortífero, incurre en sanción de diez a treinta años de privación de libertad, privación perpetua de libertad o muerte.

Artículo 11. En igual sanción incurre el que entrega, coloca, arroja, disemina, detona o utiliza de cualquier otra forma, un artefacto explosivo o mortífero, u otro medio o sustancia de las descritas en el artículo 10, contra:

- a. un lugar de uso público;
- b. una instalación pública o gubernamental;
- c. una red de transporte público o cualquiera de sus componentes;
- d. una instalación de infraestructura;
- e. cosechas, bosques, pastos, ganado o aves;
- f. campamentos, depósitos, armamentos, construcciones o dependencias militares en general.

Artículo 12. El que, adultere sustancias o productos alimenticios o de otro tipo, destinados al consumo humano, de modo que puedan causar la muerte o dañar la salud de las personas, incurre en sanción de privación de libertad de diez a veinte años.

Si como consecuencia de los hechos descritos en el apartado anterior se ocasionan lesiones graves o la muerte de alguna persona, la sanción es de diez a treinta años de privación de libertad, privación perpetua de libertad o muerte.

Artículo 13. El que, ejecute un acto contra la vida, la integridad corporal, la libertad o seguridad de alguna persona que por la naturaleza de las actividades que desarrolla disfrute de relevante reconocimiento en la sociedad, o contra sus familiares más allegados, incurre en sanción de privación de libertad de diez a treinta años, privación perpetua de libertad o muerte.

Si el acto ejecutado se dirige a destruir o dañar significativamente los bienes de que dispongan las personas a que se refiere el apartado anterior, la sanción es de privación de libertad de cuatro a diez años.

Contiene un Anexo con expresiones conceptuales a tener en cuenta en esta Ley, entre ellas:

- Por artefacto explosivo u otro artefacto mortífero se entiende:
 - b. el arma o artefacto que obedezca al propósito de causar o pueda causar la muerte o graves lesiones corporales o grandes daños materiales mediante la emisión, la propagación o el impacto de productos químicos tóxicos, agentes o toxinas de carácter biológico o sustancias similares o radiaciones o material radioactivo. (Convenio Internacional para la Represión de los Atentados Terroristas Cometidos con Bombas)

Consideramos que con la promulgación de la Ley No. 93, Cuba dio un importante paso en la modernización de su sistema legislativo dirigido a garantizar una eficaz lucha contra el

terrorismo y cumplir rigurosamente con las prohibiciones de la Convención sobre Armas Biológicas y Tóxicas.

El texto completo de esta Ley ha sido entregado por Cuba a la Secretaría, para que pueda ser consultado por todas las delegaciones interesadas.

(informal transcript of the English interpretation)

In Cuba, complementary legislation has had a very important role in the system enacted in our country to fulfil the prohibitions under the Biological Weapons Convention. I would like to state that Cuba currently implements a set of legislation in the field of public health, and with respect to the handling of dangerous substances, and in other spheres as well.

I will not go into details with respect to this complementary legislation. It is to be found in the documents which Cuba has provided to the Secretariat for consultation by delegations interested in the matter. I would like to refer briefly though to anti-terrorism in force in the country. This is one form of complementary legislation and a reply to the appeal by the Secretary General of the United Nations. As evidence of Cuba's strong commitment to the fight against terrorism in all its forms and manifestations, Cuba ratified the international conventions in the field of terrorism. In addition, three months after the terrible events of the eleventh of September in New York and in Washington D.C., the Cuban parliament adopted, in December 2001, the so-called Law 93 to combat acts of terrorism. That new law adopted in Cuba contains various provisions which are particularly intended to fulfil the prohibitions to be found under the Biological Weapons Convention, with very severe penalties for those who violate such prohibitions.

With respect to the Convention itself, the anti-terrorist law in Cuba contains, in Chapter 1, acts committed with explosive or lethal devices, chemical or biological agents or other means or substances, the following offences: Article 10 refers to the fact that persons who manufacture, facilitate, sell, transport, deliver, introduce within the country, or possess or have in their possession in any form or any place, chemical or biological agents for prohibited purposes are liable to 10 to 30 years deprivation of freedom, life imprisonment, or indeed the death penalty.

The law also stipulates that there are similar penalties for those who provide, place, deliver, disseminate, detonate, or employ in any other manner, chemical or biological agents in the following cases: in a place of public use, in a public or government facility, in the transport network of any of its components, in a facility of public infrastructure, harvest, grazing, or military facilities in general. In addition, the law stipulates that persons who contaminate food substances for human consumption or which may result in death or injury to individuals, are liable to deprivation of freedom for 10 to 20 years. If as a result of these facts a person is injured or killed, then they are liable to imprisonment of 10 to 20 years, life imprisonment, or the death penalty.

In summary, we consider that with the promulgation of this complementary anti-terrorist legislation, Cuba took an important step in the modernization of its legislation with a view to ensuring an effective campaign against terrorism and stringent fulfilment by Cuba of all the provisions in the Convention. I would just like to say that the full text of Cuba's legislation is also to be found in the documentation which Cuba has handed to the Secretariat and which is available for consultation by any delegation interested to inquire into the matter.

Spain

Spain's Comments on Anti-Terrorism Legislation

Spain had anti-terrorism legislation in place long before the BTWC existed. Spanish Penal Code criminalizes terrorist acts (including bioterrorism) as well as different types of collaboration with terrorists and even the intent to commit terrorist acts. The legislation also covers financing and money laundering. Penalization could go up to life imprisonment.

Wednesday 20 August 2003

Saudi Arabia

يسر وفد بلادي ان يتقدم لسعادتكم بالتهنئة على رئاسة هذا المؤتمر الهام ، والتي تظهر مكانتكم و أهمية بلادكم . ونحن على ثقة بقدرتكم وكفاءتكم التي ستسهم في إنجاح هذا المؤتمر . كما ان الجهود التي بذلها مكتب نزع السلاح للإعداد لهذا المؤتمر محل تقديرنا وشكرنا .

ينعقد مؤتمرنا هذه الأيام ، والعالم يمر بمرحلة هامة وحساسة مما يتطلب من المجتمع الدولي ان تتضافر جهوده السلمية الى إيجاد عالم يسوده الأمن والاستقرار ، فبدون ذلك لا يمكن لمجتمعنا البشري ان ينعم بتحقيق الأهداف السامية المنشودة والتي يتطلع إليها . ومن هذا المنطلق فان اتفاقية حظر وتطوير وانتاج وتخزين الأسلحة البيولوجية وتدميرها ، تشكل بلا شك أحد الأركان الهامة لمواجهة هذه الأوضاع الحساسة .

وفي هذا السياق فان حكومة المملكة العربية السعودية تعيد تأكيدها على ما جاء في المعاهدة .

ان قيام الأمم المتحدة والمنظمات الدولية الأخرى . بالدور المنشود منها يتطلب التزام واحترام أعضاء الآسرة الدولية للأهداف والمقاصد التي أنشئت هذه المؤسسات الدولية لتحقيقها ، والتي يلتي في مقدمتها بدون أدنى شك حفظ السلم والأمن الدوليين .

انطلاقاً من حرص المملكة العربية السعودية على التعايش السلمي بين الدول والمحافظة على مكتسباتها وإمكانياتها ، ورغبة منها

في إحلال السلام والأمن كلفة تعايش بين الشعوب والأمم ، فقد أولت حكومة بلادي اهتماماً كبيراً لمسألة انضمامها لهذه الاتفاقية والمعاهدات التي تعزز السلام والاستقرار الدوليين وتقلل مخاطر نشوب حروب تستخدم فيها أسلحة محرمة دولياً كالأسلحة النووية والبيولوجية والكيميائية . ولقناعتها بمخاطر هذا السلاح الفتاك ودعمها لتوجه المجتمع الدولي بتحريم إنتاج واستعمال ونقل الأسلحة البيولوجية ، فقد كانت المملكة من أوائل الدول الموقعة والمصادقة على اتفاقية حظر الأسلحة البيولوجية في عام ١٩٧٢ ، وتشارك بلادي في جميع أنشطة المتعلقة بالاتفاقية بفعالية ، إيماناً منها بأهدافها النبيلة والانعكاسات الإيجابية المتوقعة تحقيقها من هذه الاتفاقية ، وفي هذا الإطار فإن المملكة تدعو بقية الدول التي لم تنضم بعد إلى الاتفاقية باتخاذ الإجراءات اللازمة للانضمام إليها والحرص على تطبيقها لما فيه مصلحة المجتمع الدولي وتعزيز السلم والأمن الدوليين .

لا شك أن القضايا والمناقشات التي سوف يتناولها اجتماعنا الهام هذا سوف تسهم بشكل جوهري للاستفادة مما سوف يتمخض عنه هذا الاجتماع الهام إضافة إلى تجربة بلادي الناجحة بإنشاء هيئة وطنية خاصة بتنفيذ اتفاقية حظر الأسلحة الكيميائية . وفي هذا الخصوص فإن حكومة بلادي سوف تأخذ بعين الاعتبار الآراء والمناقشات عند إنشاء الإطار التنظيمي لتنفيذ اتفاقية حظر الأسلحة البيولوجية على النطاق الوطني ، ونتطلع أن يلي هذا التنظيم كافة الشواغل والمسائل التي

تضمنتها بنود الاتفاقية . مثل الإجراءات القانونية والتنظيمية والإدارية التي تشمل إجراءات الحظر والمراقبة وسن التشريعات الكفيلة بتحقيق ذلك . بالإضافة الى مسألة الأمن والمراقبة والأشراف وما يتفرع منها .

وختاماً نتمنى لاجتماعنا هذا التوفيق والنجاح لتفعيل دور ومهام هذه المعاهدة ، لما في ذلك من اثار إيجابية على امن واستقرار مجتمعنا البشري .

(informal transcript of the English interpretation)

Our conference is meeting today, while the world is witnessing a very delicate and very sensitive situation. This is why the international community should ensure cooperation in order to establish security and stability. Without such cooperation, humankind will not be able to realize its noble objectives which it aspires to. On this basis, the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction constitutes one of the main instruments in order to deal with this delicate situation.

In this context, the Government of the Kingdom of Saudi Arabia would like to re-emphasize the content of this Convention. The United Nations and other international organizations must carry out their goal and this is why the international community must ensure full respect for the purposes and objectives for which these institutions and organizations have been set up. One of the most important purposes is the preservation of international peace and security.

Based on the fact that Saudi Arabia is keen to peacefully coexist among states, as well as to conserve all its possibilities, gains and potential as well, and based on the fact that Saudi Arabia desires that peace and security would be a language of coexistence among people and nations around the world, so my country attaches great importance in acceding to this Convention as well as the treaties that enhance international peace and stability and reduce the threat of an eruption of a war where prohibited weapons are used, similar to nuclear, chemical and biological weapons that are internationally prohibited.

We are fully convinced of the threat of these lethal weapons and here we support that the international community would criminalize the production, use and transfer of biological weapons. Saudi Arabia was the very first country, one of the very first countries rather, which has ratified and signed the BTWC in 1972. My country takes part in all the activities related to

this Convention effectively because we believe in the noble objectives and the positive repercussions of this Convention. In this framework, Saudi Arabia calls upon all countries which did not yet accede to the Convention to do so by taking the necessary measures to accede to the Convention and also to implement this Convention in a way that would fulfil the interests of the international community, as well as enhancing international peace and security.

Undoubtedly, the issues and the discussions that will be dealt with here at this very important meeting will undoubtedly contribute substantially to benefiting from the results of this very important meeting. Moreover, my country had a very successful experience through the establishment of a national authority related to the implementation of the BTWC. In this context, the government of my country will take into consideration all the views and the discussions that took place when we establish the organizational framework to implement the BTWC on a national level.

We are looking forward that this regime and system would satisfy all the preoccupations and concerns included in the Convention. Similar to the legal, organizational, administrative measures and procedures that would also include prohibition and surveillance as well as enacting the necessary legislations to achieve the aforementioned, in addition to the issues of security, surveillance and monitoring and control. In conclusion, we wish you the best and all the success to activate the role of this Convention due to its positive impact on the security and the stability of our community and the international community.

China

Statement on National Implementation Measures: Export Control Regime

As a State Party to the Biological Weapons Convention, China has earnestly fulfilled its obligations. China has never developed, produced, stockpiled or assisted other states to acquire or develop biological weapons.

In order to reinforce the effectiveness and legalization of the export control in the biological field, China has stipulated a series of laws and regulations, such as *Regulation of the People's Republic of China on Export Control of Dual-use Biological Agents and Related Equipment and Technologies and its Export Control List*, *Customs Law of the People's Republic Of China*, *The Criminal Law of the People's Republic of China*, etc., covering the following areas:

- (1) Control List. The export control list in the biological field comprises 79 pathogens, 17 toxins and 7 categories of dual-use equipment and related technologies. The list almost covers all the sensitive biological items and has been conforming to the international practice.
- (2) Catch-all Principle. China has adopted the catch-all principle. “Where any unit or individual knows or should know that the dual-use biological agents and related equipment or technologies to be exported will be used by the receiving party directly for the purpose of biological weapons, it shall not export such items, whether included in the Control List or not”.
- (3) Registration and Licensing System. Anyone who deals with the export of sensitive biological items, whether it is export for trade, or exchange with, gift to, exhibition in, assistance to, provision of service for as such and other forms of technological transfer thereof to foreign countries and regions, shall register itself with the Ministry of Commerce. Each time when a

registered unit or individual intends to export items in the Control List, it shall apply to the Ministry of Commerce for license and provide such documents as certificate of end-use and end-user and government guarantee. The Ministry of Commerce will examine, according to actual circumstances, the application independently or jointly with the Ministry of Foreign Affairs, Ministry of Public Health or Ministry of Agriculture. If the case has significant impact on the State security and public interests, the relevant ministries shall submit the case to the State Council for approval.

(4) Customs Supervision. Where an application is examined and approved, the Ministry of Commerce shall issue a license and notify the Customs in writing. The Customs shall proceed, according to relevant laws and regulations, with the formalities and supervise the entire process so as to ensure that the category and quantity of exported items are identical with the declaration.

(5) Violation Punishment. Those who export controlled biological items without license or beyond the scope of the license without authorization shall be investigated for criminal liability in accordance with the provisions of the Criminal Law on smuggling, illegal business operations or other crimes. If such activities are not serious enough for criminal punishment, the exporters shall be punished according to relevant provisions of the Customs Law, or be given a warning, confiscated their illegal income, suspended or even revoked the licensing for their foreign trade operations by the Ministry of Commerce according to the actual situation.

For details of the above-mentioned regulations, please go to the website of the Chinese Ministry of Foreign affairs www.fmprc.gov.cn/eng/c466.html or the website of Ministry of Commerce www.mofcom.gov.cn/ckgz.shtml.

The Chinese Government has adopted various measures to ensure the effective implementation of the said laws and regulations. Inter-ministerial coordinating mechanism was set up to coordinate efforts by different departments in export control and nonproliferation. Export control training courses were arranged for the training of export control officials. Experts group was established so that experts can be consulted on technical or legal issues. Through all kinds of publicizing, training efforts, the awareness of exporters to abide by laws and regulations has been raised.

Besides, the Chinese Government has promulgated and implemented a series of export control regulations covering nuclear, chemical and missile fields. Generally speaking, by setting up a legal system and adhering to the principle that “there shall be laws to abide by, everyone should abide by the law, the law must be enforced strictly, and those who violate the law shall be dealt with”, the export control regime of China is by and large in line with international practice. The administrative management has been transformed into one of management by law.

In the future, the Chinese Government will further strengthen its efforts to publicize and implement relevant export control regulations with an aim to enforce them comprehensively and effectively. Meanwhile, we believe it's vitally important to boost international cooperation and exchanges. This will be conducive to drawing upon successful experience of the others to offset their own weaknesses, and enhancing mutual trust. The Chinese Government is willing to further expand and deepen exchanges with other countries and intensify cooperation with all States Parties in biological nonproliferation field so as to fulfil obligations of the Convention in a comprehensive and effective manner, strengthen biosecurity, prevent proliferation of biological weapons and bioterrorism and make contributions to world peace and security.

Italy

EU legal regime of controls of exports of dual use items

1) The legal framework

The main legal instruments covering export controls of dual-use items and technologies in the European Union are:

- a) EU Regulation 1334/2000 (adopted 22 June 2000 and entered into force 90 days after its publication in the Official Journal of the Community, in September 2000). Its articles 1 to 24 set the legally binding procedures applying to export controls of dual-use items in all EU Member States (thereby of application by industry and public administration).
- b) The annexes of EU Regulation 149/2003 adopted 27 January 2003 are the latest update of the lists of dual use items and technologies under control (these items cover all export control regimes to which EU Member States belong to, ie Wassenaar Arrangement, Australia Group, Nuclear Supplier's Group, Zangger Committee, Missile Technology Control Regime).
- c) Joint Action CFSP 401/2000 details the principles which national EU Member States legislations should cover regarding controls of technology transfers related to military assistance and also technology transfers occurring through the move of natural persons across borders.

2) The items controlled by the EU Export control regime

- a) The lists of items are detailed in the annex I of the Regulation 149-2003. The Commission regularly makes proposals to the Council with the view to updating the lists of items and technologies under control. Definitions are provided in the Regulation. Dual use items are defined in Article 2, certain definitions regarding chemical and biological dual use items are made in pages 11 to 17. Lists of dual use chemical and biological items under control are to be found in pages 56 to 60 as well as in pages 78 to 81.
- b) Other non listed items which can be submitted to export authorization by decision of EU Member States at national level.

EU Member States can control exports of dual use items other than those listed in the annexes of the EU Regulation (conditions set in Articles 4 and 5).

3) Who delivers the export control licences in the EU Member States

The Member States are responsible for granting the export licences and denying them (criteria non exhaustive set in article 8 of the Regulation 1334/2000 and which refer to international treaties and obligations regarding non proliferation of weapons of mass destruction). The licenses used in the Community are the Community Export Authorisation (Annex II), General (Annex IIb), global and individual licenses (Annex III a) whose common elements are set out in Annex III of the Regulation 1334/2000.

4) Controls of Intangible Transfers of Technology

Article 2biii) of EU Regulation 1334/2000 covers the controls of intangible transfers of technology except those occurring through the move of natural persons across borders. It is written as follows " export shall mean transmission of software or technology by electronic media, fax or telephone to a destination outside the Community. This applies to oral transmission of technology by telephone only where the technology is contained in a document the relevant parts of which is read out over the phone, or is described over the telephone in such a way as to achieve substantially the same result".

5) The single market for dual-use items

The freedom of circulation of dual-use items in the EU is the general rule and the list of dual use items which are subject of export controls between EU member States is defined in Annex IV of the 149/2003 Regulation. If items have to be controlled in the internal market, the conditions set in the Treaties for such situation must be made (article 28 to 30 of the Treaty).

6) Enlargement perspectives

EU Regulations on export controls of dual-use items are part of "the acquis" therefore at the time of effective entry into the EU the future EU MS will be bound by the same legal provisions as the EU Member States (core regulation 1334/2000 and lists of items which by May 2004 will integrate the decisions of export control regimes made in 2003). As part of the preparatory process, all future EU Member States have already adopted legislation in line with EC Regulation 1334/2000 and since mid April 2003 they participate as observers to all the EU meetings related to export control issues and the management of the EU Regulation on export controls.

7) Recent developments in the EU

The Thessalonique Summit of June 2003 has adopted a comprehensive action plan against proliferation of weapons of mass destruction.

Romania

National Agency for Export Control: A N C E X

Export Control Regime in Romania: Biological Items and Technologies

BTWC Requirements Regarding Transfers of Biological Items

- Article III of the BTWC
- Each State party to the BTWC undertakes not to transfer to any recipient whatsoever, directly or indirectly, and not in any way to assist, encourage, induce any state, group of states or international organizations to manufacture or otherwise acquire any of the agents, toxins, weapons, equipment or means of delivery specified in Article I of the BTWC

National Legislation

- Primary legislation – GO 158/1999
 - *Setting up a national regime for the control of exports of conventional arms/dual-use goods and technologies (including biological goods and technology);*
 - *Inter-agency cooperation (Inter-ministry Council)*
- Secondary legislation
 - List of conventional arms/dual-use goods and technologies (including biological goods and technologies)
 - Ministerial orders for implementing the law
 - Catch-all procedure (end-user oriented control)
 - Documentation (Authorization, Individual License, International Import Certificate, Non-Transfer and End-Use Certificate, Delivery Verification Certificate, applications for the documents)
 - Internal procedures

Biological Items

Romanian export control goal and objectives:

- To maintain and develop the responsible behavior of Romania in the field of Nonproliferation and Export Controls and preventing bioterrorism
- by
- Strengthening the National Export Control System
 - Consolidating the Export Control First Decade Developments
 - Improving the Primary Legislation
 - Developing the Secondary Legislation
 - Fostering the Enforcement Dimension
 - Implementing the Transparency Principle

Romanian Export Control System

Inter-Ministry Council - IC

National Agency for Export Control: ANCEX

ANCEX is the national authority in the fields of export control and control of the prohibition of chemical weapons

Basic Principles of the Export Control System

- Romania's foreign policy priorities
- National economic and security interests
- Non-proliferation of WMD, including biological weapons
- International treaties and commitments
- Principle of cooperation
- International global struggle against terrorism, including bioterrorism

Brief History of ANCEX and National Export Control System

- The primary stage: 1992- 1994
- The accumulation stage: 1994- 2001
- The development stage: 2001 -

New Primary Legislation - GO 158/1999 on the exports and imports of strategic goods
New Secondary Legislation - Update of control lists: GD 467/1999 & GD 20/2000

The Added Value of GO 158/1999

- Strengthening of the National Authority role and tasks
- Introduction of the authorization procedure
- *catch-all* procedure
- ITT control
- International transit and transshipment
- Non-commercial operations
- Sensitive and very sensitive *dual use* items
- Intelligence services involvements in decision making process
- Strengthening the sanctions

The Development Stage 2001 -

- A new administrative framework for the national authority – since January 2001 ANCEX is subordinated to the Ministry of Foreign Affairs of Romania
- The essential key tool of this new stage is the Government – Industry partnership
- Implementation of the Internal Control Program within relevant Romanian companies
- Strengthening the inter-agency cooperation within Inter-ministry Council (IC)
- Bilateral partnership with IC members
- ANCEX IT products: electronic Export Control lists, Export Control – country profiles, Euro-Atlantic Export Control *best practices*

Licensing Procedure

Activities Requiring a Licence

Evaluation of License Application

Export Enforcement's Role

Investigations and Sanctions

Enforcement Mission

Preventive Enforcement

Compliance Visits - Goal

Enforcement

Interagency Cooperation

Red Flag Indicators

Safeguard Program

Enforcement

Conclusions

Government Outreach to Industry: Romanian Experience

ANCEX Program Aims

ANCEX Program Resources

ANCEX Program: Policy and Transparency, 2001 – mid 2003

ANCEX Program: Communication (Selective) – I, 2001 – mid 2003

ANCEX Program: Communication (Selective) – II, 2001 – mid 2003

ANCEX Program: Cooperation (I), 2001 – mid 2003

Republic of Korea

In relation to the export control system, my delegation thinks that there are two somewhat conflicting goals or aims to pursue in its implementation. Those are effectiveness and comprehensiveness. On the one hand, the system must control the export of sensitive goods and technology effectively with limited resources. On the other hand, the control must cover sensitive goods and technology comprehensively.

In an effort to effectively prevent the proliferation of weapons of mass destruction including biological weapons and to comprehensively control the export of sensitive goods and technology, the Republic of Korea introduced the catch-all system into its domestic legal framework in January this year and has been implementing accordingly. Article 81 to 85 of the Public Notice regulates the non-listed dual-use goods that can be used to develop, produce, use or stockpile weapons of mass destruction and their delivery systems. It stipulates that the authorizing agency may pose a restriction on the issuing of an export license to a person who intends to export non-listed dual-use goods to the country which is developing or is suspected of developing WMD. A person who intends to export the above mentioned dual-use goods should apply for an export license when he or she received information that the export goods are used or can be used for WMD, when he or she knows that an importer is engaged in WMD activities or when the authorizing agency requests the exporter to apply for an export license.

Because we instituted the catch-all system only recently, we do not have much experience for its concrete implementation. In this respect we appreciate the explanation by the German delegation on their experience. Despite this little experience, however, we have found that the dialogue or communication between the authorizing agency and industry is vital for the successful implementation of the catch-all system.

Japan

Japan on Classification: Catch-all clauses and its import upon Japan's industry

Since Japan's pertinent industry is significantly large, Japan carries out strict export controls whose restricted item covers 87 BW related items and includes dual use items. Their export to all countries and areas is subject to licensing and custom inspection of relevant authorities. The catch-all clause is also an important part of our export control, but we have yet seen any seriously negative import upon our industry nor received any complaints from it.

Japan on Intangible Technologies

Japan recognizes the need to control intangible technologies but still exploring how it can respond to related difficulties as mentioned in your key questions or the announced agenda. One additional difficulty with Japanese authorities see is the volume of information and work. In controlling intangible technologies, we have to deal with e-mail, faxes, telephones, websites and what not and the volume of this is enormous and some may be coded. It is a difficulty which poses a large challenge to our export control authorities.

United States

Overview of U.S. Controls on the Export of Biological Agents and Related Technology

Export Controls and the BWC

- Article III
 - “Each State Party ...undertakes not to transfer to any recipient whatsoever, directly or indirectly, ...any of the agents, toxins, weapons, equipment or means of delivery specified in article I of the Convention.”

Objectives of U.S. Export Controls

- Stemming the proliferation of weapons of mass destruction
- Stemming international terrorism
- Furthering the security and foreign policies of the United States

Elements of U.S. Export Controls

- Export licensing requirements
- Specific controls depending on type of item, destination, and end-user
- Criminal and administrative sanctions for violations

U.S. Agencies Administering Export Controls

- Department of Commerce
 - Bureau of Industry and Security
- Department of State
 - Directorate of Defense Trade Controls
- Other agencies

Department of Commerce

- Export Administration Regulations (EAR)
 - Implement the Export Administration Act
 - Apply to dual-use items (i.e., items with both commercial and military applications)
 - Apply to certain activities of U.S. persons
 - Available via the internet at www.bis.doc.gov
- Scope of EAR licensing requirements

- List-based (Commerce Control List)
- “Catch-all”

Commerce Control List (CCL)

- Multilaterally controlled items
 - Treaty-based restrictions (e.g., CWC)
 - Other export control regime restrictions
- Unilaterally controlled items
 - Items controlled for anti-terrorism reasons

CCL – Biological Agents and Related Technology

- A license is required for exports to all destinations
- Human and zoonotic pathogens and toxins.
- Animal and plant pathogens
- Genetic elements and genetically modified organisms
- Equipment
- Technology
 - Specific information necessary for the development, production, or use of a product
 - In the form of “technical data” or “technical assistance”
 - Excludes publicly available technology

“Catch-All” Controls

- Apply to certain end-uses of proliferation concern
- A license is required even though a license would not be required based on the CCL

Enforcement of the Commerce EAR

- Violations of the EAR are subject to criminal and administrative penalties
- Commerce may impose civil fines or other administrative sanctions
 - Export privileges may be denied (denied persons list)

Department of State

- International Traffic in Arms Regulations (ITAR)
 - Implement the Arms Export Control Act
 - Control exports of “defense articles” and “defense services”
 - Available via the internet at www.pmdtc.org/reference.htm

USML

- Defense articles and services constitute the United States Munitions List (USML)
- All exports of items listed on the USML require a license
- Includes biological agents and biologically derived substances
 - Capability to produce casualties in humans or livestock, degrade equipment or damage crops

- Equipment for dissemination of, detection and identification of, and defense against biological agents

ITAR Policy Regarding Defense Articles or Services

- A defense article or service is so designated if it is specifically designed, developed, configured, adapted, or modified for a military application and:
 - does not have “predominant civil applications” and “performance equivalent (defined by form, fit and function) to those of an article or service used for civil applications,” or
 - has significant military or intelligence applicability such that control is necessary
- Intended use of article or service after export is not relevant in determining whether it is on the USML

Exports of Defense Articles and Services

- Exports of defense articles
 - Include oral or visual disclosure of technical data to foreign persons in the United States or abroad
 - Include software
- Exports of defense services
 - Include the furnishing of technical data to foreign persons (whether in the U.S. or abroad)
 - Include performing a defense service for a foreign person

ITAR Enforcement

- Criminal and civil sanctions under U.S. criminal law
- Administrative sanctions under the Arms Export Control Act and the ITAR

Summary

- U.S. export controls are consistent with Article III of the BWC
- U.S. export controls support the U.S. Government goal of stemming the proliferation of biological weapons
- Exports of biological agents and related technology are closely reviewed and tightly controlled by the U.S. Government
- Violations of U.S. export control laws are subject to criminal and civil sanctions

Cuba

La cuestión de los regímenes de control de exportaciones es de gran importancia para los Estados Parte de la Convención sobre Armas Biológicas y Toxínicas.

Particularmente para los países en desarrollo es un tema de importancia clave, pues en buena medida tienen que importar tecnologías de uso dual para lograr desarrollo en su esfera biotecnológica y en general de su economía.

Cuba considera que facilitar la participación más amplia posible en los intercambios y una cooperación internacional reforzada en la esfera de actividades biotecnológicas pacíficas,

dirigidas a facilitar el desarrollo económico y social, constituye un elemento vital para fortalecer la implementación de la Convención .

La existencia de regímenes de control de exportaciones que se basan en criterios selectivos y discriminatorios resulta inaceptable y representa, en la práctica, un serio obstáculo para la aplicación del derecho inalienable de todos los Estados a utilizar con fines pacíficos los diversos medios y tecnologías existentes en la esfera biológica.

Cuba considera que el modelo de control de exportaciones e importaciones más efectivo es el que se negocie y se aplique en el marco multilateral. Asimismo, todo control internacional de exportaciones e importaciones debería tener entre sus premisas esenciales la mayor participación posible de países que estén dispuestos a compatibilizar sus controles y regulaciones nacionales con el objetivo de facilitar el monitoreo de la actividad objeto de regulación. Sólo esa participación amplia y no discriminatoria puede garantizar la efectividad en el cumplimiento de los objetivos que se persiguen.

Por otra parte, Cuba siempre ha defendido el criterio de que los controles de exportación e importación de tecnologías de doble uso no son un fin en sí mismo sino una herramienta útil que poseen los Estados para impedir el desvío de esos avances científicos y tecnológicos hacia fines militares. Mantenerlos aislados de un sistema conformado por componentes de seguridad y de desarrollo sólo acentúa su ineficiencia. Es por ello que, si realmente a través de esos mecanismos se pretende impedir el desarrollo de armamentos, deben formar parte de un sistema que contemple elementos de desarme, no proliferación, verificación y cooperación internacional para el desarrollo socio-económico de todos los países, particularmente de los países del Sur.

Cuba esta convencida de que los esfuerzos multilaterales deben complementarse con medidas adoptadas a nivel nacional que refuercen los compromisos adquiridos por los Estados en el ámbito de los tratados internacionales sobre desarme y no proliferación de los cuales son Parte, incluyendo la Convención sobre Armas Biológicas. En ese sentido, la adopción de legislaciones nacionales resulta de vital importancia en la consecución de los objetivos de desarme, control de armamentos y no proliferación trazados por la comunidad internacional y, por ende, en la promoción de un clima de entendimiento y confianza mutua entre los Estados.

Siendo consecuente con las premisas y consideraciones anteriores, en Cuba existe un cuerpo legislativo y otros procedimientos que rigen toda la actividad de los diferentes organismos e instituciones nacionales que, de una u otra manera, trabajan vinculados a las esfera biológica. Dicho cuerpo legislativo se ha diseñado, y actualizado cada vez que ha sido necesario, de manera tal que Cuba pueda cumplir estrictamente con los compromisos adquiridos como Estado Parte de la Convención sobre Armas Biológicas y otros tratados internacionales pertinentes.

Cuba enfatiza en la necesidad de que los Estados Partes examinen sus regulaciones nacionales relativas a los intercambios y transferencias, para garantizar que estos son consistentes con las disposiciones del Artículo X de la Convención.

(informal transcript of the English interpretation)

I wanted to take this opportunity to talk about export controls and restrictions in a general way, because it seems appropriate to talk about this in the context of monitoring and follow-up machinery, and as all States Parties are aware, the question of restrictions and particularly export

controls is of essential importance to all States Parties and particularly essential to developing countries, since very often they depend on the imports of dual-use agents and technologies in order to be able to develop in the field of biotechnology and to develop economically in general.

Now, Cuba thinks it is essential for all States Parties to the Convention to adopt strengthened effective national mechanisms which make it possible for them to guarantee the implementation of their commitments and obligations as States Parties to the Convention. Furthermore, these actions must ensure that biological agents and dual-use technologies cannot be used for other than peaceful purposes. For example, as far as Cuba is concerned, we have some well-defined laws and procedures which govern all activities run by national entities or institutions which in one way or another relate to work in bio-related fields: measures which allow us to ensure that dual-use technologies and agents are under proper control.

At the same time, while we press for the need for national control mechanisms and national effective export control mechanisms within each state, we do at the same time think that there needs to be broad participation in national exchange, trade, and cooperation in the field of biotechnology for peaceful purposes, thus, facilitating economic and social development. It is vital to ensure the implementation of the spirit and the letter of the Convention.

Now, Cuba is rather concerned that export control regimes are sometimes based on clearly selective and discriminatory criteria; measures which we think are unacceptable and which in practice constitute a serious hindrance to the realization of the inalienable right which all States Parties to the Convention have to make peaceful use of the various means and technologies which exist in the field we are dealing with. We believe that the most effective international export control model we could aspire to is the model which applies multilaterally. We believe that any international export and import control system ought to be based on guaranteeing the broadest possible participation of the various states which are prepared to make their control and verification measures compatible in order to facilitate the monitoring of the activities we are trying to control.

Cuba has always spoken in defence of the idea that dual-use technology controls are not an end in themselves. This is something important and its something we need to emphasize. We do not, as I say, think it should be an end in itself; it should be a tool which makes it possible for States Parties to avoid these technologies and elements being used for military purposes. So, I felt it useful to present these general comments. I am quite well aware of the fact that this is a subject which does not enjoy consensus amongst all the States Parties, but it did seem at least useful to raise this and talk about it, and following the creation of the new monitoring and follow-up machinery we are taking part in we hope that we can make further progress and that we can produce specific recommendations based on consensus.

Thursday 21 August 2003

Jordan

اشكركم على اعطائي الفرصة للحديث.

1. في البداية اود ان انقل تعازي وفد بلادي الحارة بوفاة الدبلوماسي الكبير السيد سيرجيو فيرا ديميلو ، حيث كان يقوم بعمله الجاد في بغداد ومن حيث التوقيت فلم نكن بعيدين كثيراً فقد وقعت سفارة بلادي في بغداد لحادث مماثل قبل اسبوعين ، الامر الذي يدعونا جميعاً كأمم متحدة ان نعزز سبل وحدتنا في مواجهة هذه الاحداث وان نرفضها ونشجبها.
2. كما واود ان انقل لكم تهاني وفد بلادي بمناسبة تروؤسكم لاجتماعات جلسة الخبراء هذه والتي بفضل خبرتكم الكبيرة ستسفر عن نتائج هامة.
3. كما ويغتنم وفد بلادي هذه الفرصة لبيان مرتكزات الموقف الاردني الرسمي من اتفاقية حظر وانتاج وتطوير وتخزين الاسلحة البيولوجية والتكسونية والعمل على تدميرها والتخلص منها:

أ- ان الاردن قد عانى الكثير من الحروب وويلاتها وهو بالتالي يعرف ويقدر قيمة الامن والسلام.

ب- ان الاردن هذا البلد الديمقراطي بقيادته الحكيمة المعتدلة قد وقع على كافة الاتفاقيات والمواثيق الدولية الداعية الى السلام وهو مشارك فاعل في كافة نشاطات ضبط التسلح والامن الاقليمي.

ج- لم يقيم الاردن عبر تاريخه الطويل باستخدام الاسلحة البيولوجية وليس لديه اية قدرات في مجال استخدام هذه الاسلحة.

د- الاردن عضو في الاتفاقية وهذ يؤيد كافة الجهود الرامية لدعم وتقوية الاتفاقية بما في ذلك اجراءات بناء الثقة ويشارك بتقديم بياناتها بشكل سنوي.

هـ-

هـ - يشعر الاردن بالقلق لعدم توقيع بعض الدول على اتفاقية حظر الاسلحة البيولوجية وخاصة بعض الدول المجاورة ، وعلى الرغم من احتفاظ الاردن بعلاقات جيدة مع الجميع الا انه يعتبر عدم توقيع تلك الدول على الاتفاقية يشكل تهديداً محتملاً لأمنه واستقراره.

و- يرغب الاردن الى ان يتم النظر الى كافة اسلحة الدمار الشامل بنفس المعيار وان يتم بذل جهود متزامنة ومتساوية نحو حظر هذه الاسلحة ودعوة الدول المالكة لها للتوقيع على اتفاقياتها.

4. لقد قدم المشرع الاردني الكثير من التشريعات التي تخدم في تفسيرها وتدعم في بنودها اتفاقية حظر الاسلحة البيولوجية.

أ- فيما يتعلق بالارهاب ، فقد وقع الاردن عبر تاريخه الطويل ضحية للكثير من العمليات الارهابية على الرغم من يقظته في هذا الاتجاه واحباطه للكثير من هذه العمليات قبل تنفيذها داخل الاردن وخارجه.

فقد تضمنت التشريعات انزال عقوبات صارمة تتراوح بين الحبس عدة سنوات وحتى الاعدام لكل من اقترف اعمالاً ارهابية تتعلق بتدمير الممتلكات ، والاعمال الارهابية المميتة المسببة للاعاقة ، وتصنيع ونتاج المواد المتفجرة والحارقة والسامة والمستخدمه في الاعمال الارهابية ومنها المواد الكيماوية والبكتريولوجية كما يتعاون الاردن في مجال تبادل المعلومات في هذا المجال.

ب- كما أصدرت وزارة الصحة قانون الصحة العامة لعام 2002 والذي يضبط المواد والأمكنة الموبوءة الناقلة للمرض بالإضافة للأشخاص الموبوءين، كما تنظم عمل المختبرات وتداول العينات والتخلص منها كما تم إصدار تعليمات إدارة النفايات الطبية والتخلص منها.

ت- كما أصدرت وزارة الصناعة والتجارة قانون الإستيراد والتصدير لعام 2001 بحيث تتطابق إعداد المصدرة والمستوردة مع متطلبات السلامة العامة ومراعاة الإتفاقات الدولية.

5 هنالك خطة أردنية للإستجابة إلى الحوادث البيولوجية، وتتعلق هذه الخطة بالإجراءات الواجب إتخاذها عند حدوث حادث بيولوجي ناتج عن وصول عوامل بيولوجية ممرضة أو اجزاء منها أو إفرازاتها السامة إلى الهواء أو الماء أو الغذاء أو التربة.

6 إن الدول الأطراف في هذه الإتفاقية قد تعهدت وصممت على أن تعمل معاً بإتجاه تحقيق تقدم نحو الوصول لنزع سلاح كامل بما في ذلك حظر وإزالة جميع إسلحة الدمار الشامل.

(informal transcript of the English interpretation)

My delegation takes this opportunity as well to express the official Jordanian position vis-à-vis the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction.

Jordan has suffered a lot from war and its scourge, and so we know perfectly well the value of peace and security. Jordan is a democratic country, and under its prudent moderate leadership has signed a number of international conventions and treaties that call for peace and we actively participate in all the activities of regional security as well as arms control. Jordan, during its long history, never used biological weapons and has no capabilities in the use of such weapons.

Jordan also is a State Party in the Convention, and we support all efforts made to enhance the Convention, including confidence building measures (CBMs), and we also on an annual basis make declarations in this respect. Jordan is very concerned vis-à-vis the fact that some countries did not sign the BWC, particularly some neighbouring countries. Despite the fact that Jordan has very good relations with all, however, we think that the fact that such countries which did not sign the Convention do carry a possible threat to the security and stability of the region. Jordan hopes that also our view vis-à-vis the weapons of mass destruction would be regarded simultaneously together with these weapons, and we call on the states that have these weapons to sign the relevant conventions.

The Jordanian legislators have already enacted a number of legislations that do support BWC. Concerning terrorism, Jordan has fallen for a number of years throughout history a victim of terrorist attacks despite it being alert to this and despite the fact that it did abort a number of these terrorist operations before they were implemented be it inside or outside Jordan. Such legislations include severe penalties ranging from a number of years in prison and the death penalty, for anyone who commits terrorist attacks related to the destruction of property as well as deadly terrorist actions that may lead to partial or whole disability, and also that involved the manufacture and production of explosives, incendiary, toxic weapons that are used in terrorist attacks, including chemical and bacteriological agents. We also cooperate in the field of exchange of information in this respect.

The Ministry of Health has enacted the Law of Public Health of 2002, which controls infected places that are vectors for communicable diseases in addition to those who are infected with epidemics. These places are controlled by the Ministry of Health, and also it organizes laboratories and sample exchanges, and their disposal. Directives have been issued also on the management of medical wastes and their disposal.

The Ministry of Industry and Trade has also enacted the Import/Export Act of 2001. The articles of this Act are commensurate with the import/export items and with the requirements of public safety. We have a plan to respond to biological accidents and we have taken already necessary measures in case of biological incidents related to some pathogens or even toxic leakage into the air or sea or food or soil.

Member states in this Convention have been determined and undertook to work together in order to realize progress for complete disarmament including the prohibition of the use of weapons of mass destruction and also their disposal and eradication.

Japan

Practical Implementation and Enforcement in Japan

The relevant ministries to the BWC Implementing Law are 7 in total in Japan, consisting of the ministry of Foreign affairs, the Ministry of Health, Labor and Welfare, the Ministry of Education and Science, the Ministry of agriculture, Forestry and Fisheries, the Ministry of the Economy, Trade and Industry, the Ministry of Justice and the Defense Agency. Each ministry takes necessary measures within its competence. For the coordination among these ministries, a liaison conference has been established under the Cabinet Secretariat. Law enforcement in Japan is provided by the Police agency. The Police Agency is not included in the 7 ministries relevant to the BWC Implementing Law in Japan, however, it shall be informed when the other ministries get any information on BW-related activities.

The Rationales of Japan's National Infrastructure

The BW related pathogens and toxins exist in numerous institutions in different sectors in Japan. They are in the responsibility of 7 ministries and agencies.

To exercise the effective control in accordance with the BWC, we need trained staff and institutional expertise. On ratifying the BWC, Japan has decided to utilize the existing governmental institutions and designed the above-mentioned seven ministries and relevant authority to the BWC implementation.

Practical Implementation and Enforcement (Regional Approach)

Japan has taken the advantage of existing regional arrangements and framework in sharing our experience finding with Asian Pacific countries. For instance, one week after this expert group meeting, Japan will host a seminar in NBC terrorism, focusing on crisis and consequence management next month, inviting 30 participants from ASEAN countries. The seminar will cover the issue of security of biological and chemical agents and the discussion and findings in this meeting will also be introduced to the regional focal points in counter-terrorism.

Czech Republic

Approach of the Czech Republic to Implementation of Commitments to the BTWC

Outline of the presentation

- Brief outline of the legislation adopted (the BTWC and Action against terrorism)
- Establishment of the National Authority for the implementation of the BTWC
- Basic principles of the Act No.281/2002 Coll. and its implementing Decree
- Current status of the Act No.281/2002 , which is being brought into line with the practice

The Czech Republic - member state of the BTWC

Former Czechoslovakia:

- has signed the BTWC 1972
- has ratified the BTWC 1973
- the BTWC has entered into force 1975

The Czech Republic 1993

- through the Act No. 4/1993 Coll., the Czech Republic has undertaken rights and commitments of the Czechoslovakia to international law

Legislation

- The Act on Prohibition of Biological Weapons 2002
- The Act on Control of Exports and Imports 1997
- Other Acts (see Annex 2)

The measures against terrorism

The measures against terrorism include:

- National Plan of Action against Terrorism
- Basic National Civil Protection System against Highly Hazardous Biological Agents or Toxins
- Coordination - the Ministry of the Interior of the Czech Republic (E-mail: oro@mvcv.cz)
- The role of the Czech army in terms of bio-terrorism protection will be subject of the presentation by Mr. Bajgar, the Czech Armed Forces specialist, next week

SONS - the National Authority

The State Office of Nuclear Safety (SONS) is the National Authority for the supervision of the observance of biological weapons prohibition:

- Independent Central Administration Authority
- Performs supervision of the following areas:
 - Nuclear weapons non-proliferation
 - Chemical weapons prohibition
 - Biological weapons prohibition

The Act No. 281/2002 Coll.

- Establishment of the governmental administration body to perform supervision of the observance of biological and toxin weapons prohibition
- Establishment of the governmental record keeping
- Handling of highly hazardous biological agents and toxins is possible only with the appropriate licence
- Defining governmental control and supervision over the handling of highly hazardous and hazardous biological agents and toxins
- Defining inspectors' authorities and creation of the legal frame for international inspections

- Establishment of penalties and other sanctions for the violation of the obligations stipulated by this Act

Decree No. 474/2002 Coll. (1)

- List of highly hazardous biological agents and toxins
- List of hazardous biological agents and toxins
- Conditions determining a professional qualification for activities related to the handling of highly hazardous biological agents and toxins
- Particulars on the record keeping and on the data contained in declaration

Decree No. 474/2002 Coll. (2)

The lists are based on:

- List contained in the verification protocol
- Czech Republic legislation lists, which reflect the recommendations of the WHO, FAO, OIE and the EC requirements
- Recommendations of Czech professionals from the areas of human and veterinary medicine, phytosanitary sciences and environmental protection

Handling of highly hazardous biological agents and toxins

Handling of highly hazardous biological agents and toxins (HHBAT)

- Handling shall be possible only with licence
- Only for peaceful purposes
- Licensee is obliged to:
 - handle HHBAT in such a manner that they cannot be misused or stolen
 - submit a declaration to the Office within set time limits
 - transport HHBAT only in special transport packaging and in manner laid down by separate regulation
- Licensee shall keep records associated with handling of HHBAT
- Licence applicant has to appoint his/her responsible representative

The handling of hazardous biological agents and toxins differs:

- Licence issued by the Office is not required
- Handling – shall be reported in the form of declaration
- Responsible representative does not need to be appointed
- Other responsibilities are the same as those of the holders of licences

Organizational and technical measures

Up to the 15th August 2003:

- Search for attached organizations
- Seminars and training courses
- Collecting the respective data about facilities which handle the stipulated biological agents and toxins
- SONS has issued 37 licences for the handling of highly hazardous biological agents and toxins
- 8 licence applications for the handling of highly hazardous biological agents and toxins are still being reviewed
- Preparing the technical support for the national inspections

Technical support of inspection activities

- Cooperation with the reference laboratories operated by the Ministry of Health and the Ministry of Defence
- The State Institute of Nuclear, Chemical and Biological Protection (SÚJBCHO) – a mobile laboratory and a stationary laboratory with high and maximum biological containment units BL-3 and BL-4
- Establishment of database for biological agents or toxins detection and identification
- Research projects aimed at detection, identification and decontamination

Conclusion

The Czech Republic:

- Fulfils the commitments to the BTWC
- Has never possessed, produced nor developed biological weapons
- Has adopted legislative measures to prevent the misuse of biological agents and toxins
- Has established the State Control and Supervision System to ensure peaceful utilisation of biological agents and toxins

China

Statement on National Implementation Measures: Practical Implementation & Enforcement

In order to effectively implement the Biological Weapons Convention, China has set up an inter-ministerial coordinating mechanism. It's composed of Ministry of Agriculture, Public Health, Commerce, Foreign Affairs and Customs and led by the Ministry of Foreign Affairs. As for the actual operation, all the relevant ministries bear their own responsibilities in accordance with prescription of the State Council; meanwhile, they always have a close cooperation. It's the case both in export control and non-proliferation fields. Now I will give a brief introduction on the relevant management measures for export control and the ministries' division of responsibilities.

1. The management measures on the articles prohibited from import and export

China has lists animals and plants with dangerous pathogenic bacteria, injurious insects and other harmful organisms and many kinds of poisons in the *List of Articles Prohibited from*

Import and Export and prohibits their import and export. This List is modified and promulgated by the Customs General Administration of China.

2. The management measures on the articles restricted from import and export

China applies license system on the articles restricted from import and export. These articles, which cover the sensitive items including dual-use biological agents and related equipment and technologies, could be imported and exported only after authorization of the Ministry of Commerce. Ministry of Commerce is responsible for supervising and evaluating the import and export situations and reporting regularly to the State Council. China may apply temporary measures to restrict or prohibit the import and export when needed.

3. The registration measures on export of sensitive articles

Anyone who deals with export of the sensitive articles shall register itself with the Ministry of Commerce. Without such registration, no unit or individual shall export such articles. *The Management Measures on the Registration of Export of Sensitive Articles and Technologies* has prescribed these in details.

4. The management measures on license

Bureau of Quotas and Licenses is responsible for the management and supervision of the national license issuing under the authorization of the Ministry of Commerce. Those who intend to export articles in the *List of Articles under License Management* shall go to the relevant issuing organs appointed by the *Category of the License Issuing Classification* to apply for license. Related documents need to be shown at the applying time according to the *Management Measures on License*.

5. The supervision measures of the Customs

As for the articles restricted from import and export, the Customs will not let them pass on the condition without license. The Customs could also supervise the articles prohibited or restricted from import and export according to the relevant laws and regulations.

6. The punishment measures

Those who import and export prohibited articles, or restricted articles without authorization shall be investigated for criminal liability in accordance with the provisions of the Criminal Law on the crime of smuggling; if such activities are not serious enough for criminal punishment, they shall be punished according to the relevant provisions of the Customs Law. Ministry of Commerce could revoke the licensing for their foreign trade operations.

Republic of Korea

In relation to the national infrastructure for the implementation of the Convention, my delegation believes that two factors are the most important to be taken into account whatever form of national infrastructure a country may have. Those are (i) a constant review of national

infrastructure or mechanism to keep up with new threats or challenges in the implementation and (ii) regular coordination among the domestic agencies to prevent duplication or loopholes.

The Republic of Korea has been reviewing its national infrastructure for the implementation of the Convention. As we talked many times in this Meeting, we instituted the catch-all system in January this year, and this system is the result of such a review.

We have division of labor among the many ministries in the government, in relation to the implementation of the Convention. This division is mainly categorized into three fields. First, the crimes for the activities prohibited by the Convention is being dealt with by the Ministry of Justice and the Attorney General's department. Second, The Korean Ministry of Commerce, Industries and Energy is responsible for approving the controlled export of dual-use goods and technology. The Ministry must consult with the Ministry of Foreign Affairs and Trade whenever a further review or diplomatic consideration is necessary. The Korean Customs Service is in charge of enforcing export and import control at the customs level, so to speak at a working level. Third, the laws and regulations related to the safety and security of biological agents and toxins are administered by the Ministry of Health and Welfare and the Ministry of Agriculture.

My delegation believes that extensive coordination and cooperation among domestic agencies and international export control regimes is very important for the implementation of the Convention. In the Republic of Korea, there are there kinds of coordination mechanism. The overall coordination is carried out by the Ministry of Foreign Affairs and Trade. The coordination related to export control and safety and security of biological agents and toxins are carried out mainly by the Ministry of Commerce, Industries and Energy and the Ministry of Health and Welfare respectively.

Brazil

Comments on Chairman's remarks on Government-IGO cooperation, such as using mandatory national reporting to certain international organizations, for the purposes of the BWC

Humanitarian international organisms should not be used to investigate the use of biological weapons in lieu of a verification mechanism under BWC.

It stands to reason that Brazil supports the strengthening of the above-mentioned organizations but it considers that such strengthening must be sought according to their respective core mandates, lest their effectiveness and legitimacy in achieving their fundamental missions be compromised. Law enforcement is not part of their mandate. Attention should be given in this connection to aspects such as the impartiality of actions and the sovereign equality of states.

Comments on agenda item "Education and Training"

Brazil took part in organizing and subsequently hosted the first "UNMOVIC Advanced Training Course in Biology", which was held in April/May, 2003 as part of the training process of new UNMOVIC inspectors. The course was supported by two major Brazilian vaccine-production plants, for both human and veterinary use. Ten UN-selected students, from as many countries, attended the course. Teaching staff included Brazilian and Dutch scientists, as well as UNMOVIC staff. The purpose of the course was to familiarize students with the identification

and monitoring of key equipment used in the manufacturing aerobic and anaerobic vaccines, as well as in culture-cell viral vaccine production.

Brazil established in 2003 a Bio-defense Working Group under the Foreign Relations and National Defense Chamber of the Presidency of the Republic. The Working Group is in charge of coordinating government action and exchange information with a view to, inter alia, the implementation of the BWC and preventing acts of bio-terrorism. Among its awareness-raising activities, the WG is implementing a program of visits that includes talks at key institutions in the biological area.

A working group was established in 2002 by Ministerial Instruction to draft an Ethics Code for Genetic Manipulation.

Bulgaria

I would like to share with all participants of the meeting how is organized the work in Bulgaria with different microorganisms and especially with dangerous pathogens in the field of research on experimental and clinical level. From couple of years it is well established practice before to start work with different microorganisms the program of the research project to be discussed not only by the experts of the relevant scientific counsels but compulsory in the special Ethic commissions which are founded in each Research institution.

The Ethic commissions are obliged to assess not only the need and the type of the used experimental animals, the measures for prevention of environment from any kind of pollution – mainly of bacterial contamination, the measures for prevention the working staff of infections but what is important from the point of view of our discussions – the bacteria or other bio-hazardous materials which are intended to be used in the proposed study.

By this way on highest possible professional level we are able to take preliminary measures and all needed precautions for save work without risks for dissemination of some dangerous pathogens in the laboratory or in the environment according the requirements of Good Laboratory and Good Clinical Practices as well as the existing official documents in this field. This procedure is regulated with a special order of the Ministry of Health, Ministry of Education and Science and the ministry of Social affairs of Bulgaria.

Friday 22 August 2003

United Kingdom

NaCTSO – National Counter Terrorism Security Office

My talk today is about enforcement and security in the arena of pathogens and toxins.

I am not in any way an expert on pathogens and toxins or as we call them in my Department, BUGS. My colleagues and I are however specialists in security measures. By security I mean protective security which has already been alluded to in some of the break out sessions.

We have a saying in the UK that charity begins at home. We believe this is also true for protective security.

Today's Objective

- Outline police response to ATCSA 2001 legislation
- Overview of NaCTSO & CTSA
- Partners
- Action
- Industry response
- Future?

- You have already heard from my colleague Richard Binder from the UK Home Office and I will try not to go over ground that has already been covered.
- The police were given the responsibility of reviewing security at Labs and with this in mind I will go over some of the methodology involved in the process of delivery.
- Brief overview of structure NaCTSO & CTSA's and how we operate under and with Government and within Association of Chief Police Officers (ACPO) structure.
- Outline the importance of partners.
- Give you an insight into how we took action.
- Tell you how we think the scientific/academic community is responding.
- Lastly, touch on how we see the future.

Role of NaCTSO – National Counter Terrorism Security Office

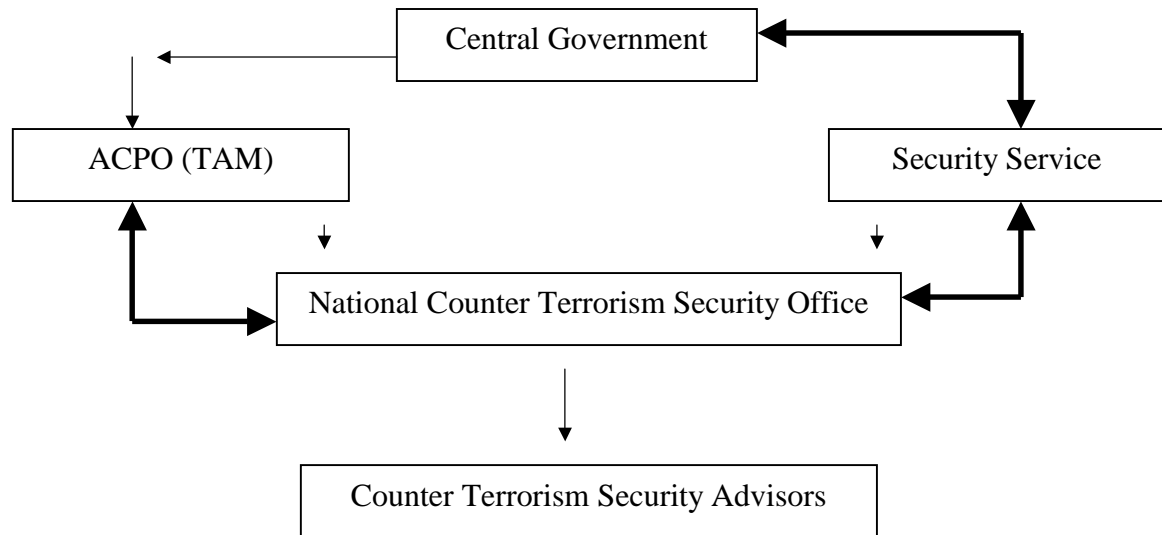
Translates into:

- Dissemination of national police policy for counter-terrorism.
- Co-ordination of CTSA activity.
- Identification of emerging needs and requirements.
- Collation of CT protective security advice and good practice.
- Provision of training for core providers.

There was a fragmented response to terrorism across the UK prior to 9/11 particularly outside London and other major cities. Lip service provided to CT work in some areas.

NaCTSO was created by ACPO TAM to redress this in June 2002. Increased resources and established a dedicated network of CTSA in each force area who have specific responsibility for protective security issues.

NaCTSO perform the above plus provide active support and advice in key areas, including P&T and other sectors that we feel may be vulnerable to terrorist attack.



The Government and ACPO TAM make CT policy with the security service. NaCTSO report directly to ACPO TAM and work alongside the security service. Both NaCTSO and the Security Service sit on the various government cabinet office groups who co-ordinate activity. NaCTSO deliver advice through the CTSA network. So you can see there is a flat management and delivery network.

NaCTSO then obtain management information from the CTSA and feed this back up the food chain thus ensuring that the process is monitored and changed if necessary.

Counter Terrorism Security Adviser

Post Sept 11th UK Response

- Identification of new vulnerabilities
- Consolidate experience to meet new threat
- Revised tactics

The UK and other countries acted to identify vulnerable areas in the light of 9/11 and one of these areas was pathogens and toxins. You have heard from our Home Office representative about the continued use of the export control legislation.

We in the UK have unfortunately had many years experience of terrorism but having said that we still need to examine our practices in the new areas traditionally thought unthinkable. We are able to use that experience and build upon it to ensure we are even more resilient to the ever present danger and threat from the new global terrorists.

The post of CTSA builds on our experience and strengthens our local and regional links with all police forces across the UK and we hope internationally. We would be only too keen to share our measures with like-minded states. The practical advice and encouragement of CTSA's at a local level will ensure our messages get to where they are needed.

Counter Terrorism Security Adviser

- ATCSA 2001 – Laboratory security.
- Advise "trusted contacts" of changes in threat and give suitable advice.
- Resolution of security concerns – NaCTSO.
- Local focal point for security guidance advice and policy development.

I will not go over the Act but remind you that a police officer in the UK can inspect a Lab and tell the lab to take measures to secure pathogens and toxins (P&Ts). They can also demand information on pathogens and toxins and the persons who have access to them. There are powers to prevent access. These powers will be used sparingly but however, are there.

One of the other main aims is to develop trusted contacts within the scientific community and should there be any changes of threat or there are concerns about any person who has access to P&Ts then prompt action can be taken.

Should there be any dispute between the local CTSA and the Lab then NaCTSO will perform a mediation role to resolve any issues. I also remind you about P&T Appeals Commission who would make the final decision on any case of denial of access.

NaCTSO is the focal point for our partners and the CTSA's and will advise and assist to develop policy with the Government and the SS.

Important Partners

- Current regulation
- Interaction – Agencies & Law
- Working together
- Develop a strategy

The police were tasked with the implementation of this legislation. The police did not know much about this area of expertise. There was a very steep learning curve for both NaCTSO and the local officers. We had to examine the current regulations in the light of the new primary legislation and see where the gaps were.

The only way to do this was developing strong partnerships with other regulatory bodies such as HSE who you will hear from next week. We have also developed suitable training in consultation with our partners.

Although these bodies had some dealings with police there was not a close working relationship. But this has changed dramatically since the legislation was introduced and CTSA's and HSE and other officials now work hand in hand with each other using each other's expertise to ensure the job gets done.

The police owe much to our new partners who have helped develop our strategy to ensure we get the industry on our side. We have a tradition of co-operation and find that tact and good humour which is a byword for UK policing is still a very effective tool, and combined with a lever, i.e. the legislation, this enables us to achieve our goals.

Action on the Ground

- Notification from Laboratories
- Police action – distribution to forces
- Introductions
- Develop standards
- Re-visit & review security at each lab
- Advice to customer
- Personnel procedures & policies

Once the Lab notifies the HO the details are passed to NaCTSO for collation. The labs are sorted into force area and that force area's list is sent to them for action. Only the SS know the entire list of labs.

The CTSA then visits, introduces him/herself and conducts a security survey. The lab and the CTSA then work together to achieve the standard required. NaCTSO and SS have developed a minimum standard of security for labs which must be achieved in a reasonable timescale. This new standard has also taken into account forthcoming EU regulations on security standards.

The CTSA monitors activity to ensure the security measures are implemented and will provide further advice where necessary on personnel checking procedures and policies. The whole process is also monitored through NaCTSO and Government Cabinet Office with regular reports on progress being submitted for government ministers.

The Industry Response

- Initially sceptical
- Culture change
- Hearts & Minds
- Acceptance?

As you may imagine there was a cultural difference between academia and the police and the initial response was "big brother" interference. However, since the industry has seen a change in attitude and awareness about terrorism in the scientific community/industry, has been raised significantly. This soft approach was deliberate, and part of the overall strategy to win over the close community involved. This ultimately, makes our job easier to accomplish.

There is still an ongoing strategy to win over the hearts and minds throughout the industry and this is vital for us to achieve our objectives – which quite simply is to make it harder for the terrorist to obtain P&Ts or to gain the knowledge on how to manufacture P&Ts and use them against us.

The Future

- More police activity in "non-traditional" sectors
- Develop new partnerships
- Raised awareness in sectors
- Difficult arena to operate
- Increased security – physical/other
- Lower risk from attack

We are already seeing police activity in non-traditional roles and areas and this will continue as the terrorist seeks new ways to attack us. By working with other partners and agencies we have raised awareness of the threat from terrorism in the various sectors and in general, and have increased the levels of physical and other types of security at labs.

This will make a difference and already has. It will make life more difficult for the insider terrorist or the terrorist attacker to operate and thus make us safer and more resilient to attack.

United States

U.S. Criminal Enforcement of Biosecurity Measures

Enforcement is Shared Among Agencies

Different agencies within the U. S. government are responsible for enforcement of biosecurity regulations that fall in the purview of their agency. Examples include:

- Plant and Animal Pathogens - U. S. Dept. of Agriculture
- Human Pathogens – U. S. Dept. of Health and Human Services.

Enforcement of Human/Public Health Issues

- This presentation will use the human health/public health example as a case study.
- Some of the implementation measures are common to all, while others may differ based on the agency in charge of the investigation or enforcement process.

Overview -- Role of Law Enforcement

- Prevention through prosecution
- Enforce prohibitions against biological weapons and regulations governing the transfer of select agents
- Inter-agency (federal/local) and international cooperation

A Successful Enforcement Strategy: Two Pillars

- Effective Legal Prohibitions
 - A. Weaponized Biological Agents
 - B. Controls Governing Transfers of Agents

- Effective Investigative Plan
 - A. Domestic Coordination
 - B. International Coordination

Pillar One: Prohibitions Against Biological Weapons

- Implementation of the Biological Weapons Convention [18 U.S.C. § 175]
- A comprehensive prohibition against involvement with biological weapons
- Prohibition against development, production, stockpiling, transfer, possession, acquisition

Pillar One: Prohibitions Against Biological Weapons

- Deterrence: significant statutory penalty
- Broad reach: definition of “biological agent” & “toxin” and extraterritorial jurisdiction
- Inchoate crimes: threats, attempts, conspiracies

Pillar One: Prohibitions Against Biological Weapons

Setting Boundaries for Unlawful Activities

- indicators of criminal intent
 - (1) possessed for use as a weapon
 - (2) possessed in such a quantity or type not justified by a legitimate purpose

Pillar One: Prohibitions Against Biological Weapons

- General Prohibition Against Weapons of Mass Destruction [18 U.S.C. § 2332a]
- Illustrations (including the “hoax problem”)

Pillar One: Prohibitions Against Control Violations

Promote Registration & Prevent Illicit Transfers

- Creation of a select list of agents & toxins with transfer and registration requirements
- Criminal prohibition against certain categories of individuals from possessing such agents [18 U.S.C. § 175b]

Pillar One: Prohibitions Against Control Violations

- Background checks & registration
- Penalties: imprisonment, fines

Pillar Two: Effective Investigation

Domestic Issues

- Federal Bureau of Investigation (FBI) is lead agency re. criminal investigative responses of national significance
- Coordinate with public health authorities (national/local)

Pillar Two: Effective Investigation

Public Security v. Public Health

- Determine threats to public safety and neutralize such threats
- Traditional investigative tasks -- crime scene preservation, evidence collection, interviews, arrests
- Overlap of roles -- necessity to coordinate efforts (joint interviews, chains of custody, media)

Pillar Two: Effective Investigation

The International Dimension

- Bi-Lateral Extradition Treaties
- Interpol
- Mutual Legal Assistance Treaties

China

Statement on National Implementation Measures: International Judicial Cooperation

The implementation of international conventions, especially arms control and disarmament conventions, is a comprehensive, systematic project which requires high technical standards and covers a wide range of areas. States Parties, while fulfilling the obligations on their own, should exchange views and cooperate with other countries in order to draw upon others' good experiences in order to offset their own drawbacks with an aim to jointly implement the Convention. Taking this into account, China has all along laid great emphasis on, and engaged itself in all kinds of international exchanges and cooperation in an open manner and good results have been achieved.

The Chinese Government also attaches great importance to international judicial cooperation. China has been cooperating effectively with the International Criminal Police Organization. China has signed more or less sixty judicial assistance or extradition treaties with other countries, which provide a powerful legal framework for the combat against transnational crimes and terrorism. Among which the punishment of violations to the Biological Weapons Convention is included.

Brazil

Comments on agenda item "Criminalization and Law Enforcement"

Article 267 of the 1940 Brazilian Penal code makes it a crime to cause a disease outbreak by propagating pathogenic germs.

More recently, Law 8072 of 1990 included this crime among “hideous” crimes that carry compulsory imprisonment and are not entitled to bail, merci or amnesty. Penalties for heinous crimes such as propagation of pathogenic germs that result in death are doubled or trebled to up to 30 years of imprisonment.

Law 8072, along with Law 7170 of 1983, which characterizes crimes against national security, social and political order, and hostile acts against Brazil, are a fundamental part of Brazilian legislation to fight terrorism. Legislation on money laundering with specific language concerning terrorism was also enacted, e.g., Law 9613 of 1998.

The Penal Code also includes the following relevant Articles that are applicable for the purposes of the BWC:

- 129 – to jeopardize the physical integrity or the health of another person;
- 131 – to intentionally commit an act that may cause one’s serious disease to be transmitted to someone else by means of contagion;
- 132 – to expose someone’s life to direct and imminent danger;
- 259 – to disseminate an illness or plague that may cause damage to forests, plantations or animals of economic relevance;
- 268 – to violate a determination by public authorities aimed at impeding the introduction or propagation of a contagious disease;
- 269 – to fail to notify public authorities of a case of a disease subject to mandatory notification (applicable to physicians);
- 270 – to poison drinking water for public or private use, as well as edible or medical substances destined for consumption.

Other relevant legislation regulates Genetic Manipulation, Biological Pest Control and the Protection of Biodiversity. Brazilian legislation is periodically submitted to the UN under the Confidence-Building Measures mechanism of the BWC and is available on the Internet, e.g.:

- www.ctnbio.gov.br.

Brazil submitted a report on law enforcement and other governmental measures to the Counter-Terrorism Committee on the implementation of the United Nations Security Council Resolution 1373 of 2001 (Document S/2001/1285), which is also available in the Internet:

- www.un.org/docs/sc/committees/1373/submitted_reports.html

Monday 25 August 2003

United States

Overview of U.S. Efforts in Pathogen Security

Background

- The United States began work on effective measures to protect against unauthorized access to dangerous pathogens in the early 1990's
- These efforts are consistent with our obligations under the Biological Weapons Convention.
- Recent events in the United States and Japan have demonstrated the importance of these efforts.

Major Tasks Accomplished

The United States has:

- defined the agents to be regulated ("select agents").
- established appropriate enforcement measures.
- identified technical and legal experts.
- developed specific guidelines for work with select agents.
- has established procedures for safe and secure transport of pathogens.
- identified national bodies for oversight.
- established procedures to maintain and monitor security of pathogens.
- developed procedures for emergency response.

Many of these topics will be elaborated further in presentations later this week.

Identification of Select Agents/Toxins

- The Department of Health and Human Services (HHS), through its Centers for Disease Control and Prevention (CDC), working with other United States Government Agencies, identified a list of select agents/toxins relevant to human disease.
- The U. S. Department of Agriculture, in consultation with other Agencies developed select agent lists for animals and crops of economic significance.
- Both lists were published in accordance with the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.
- A combined list of all US select agents can be found at the following website:
www.cdc.gov/od/sap/docs/salist.pdf

Risk Assessment

- Thorough risk assessment is essential to U. S. biosecurity efforts.
- Risk assessment encompasses consideration of all vulnerabilities to pathogen/toxin security and their consequences.
- Risk assessment must be facility-specific, however, the U. S. has identified critical components common to all facility risk assessments.

- Security plans should be developed based on the findings of the risk assessment plan.

Common Components to Risk Assessment

- Physical facility vulnerabilities.
- Personnel vulnerabilities.
- Informational/Inventory/Recordkeeping vulnerabilities.
- Procedural/Operational Vulnerabilities.
- Analysis of Facility Mission

National Measures Adopted by the US

- The Biological Weapons Anti-Terrorism Act of 1989.
- The Chemical and Biological Weapons Control and Warfare Elimination Act of 1991.
- The United and Strengthening of America by Providing Appropriate Tools Required to Intercept and Obstruct Terror (USA PATRIOT ACT) of 2001.
- The Public Health Security and Bioterrorism Preparedness Act of 2002
- The Agricultural Bioterrorism Protection Act of 2002.
- We will refer to these two acts together as the Bioterrorism Acts of 2002.

Impact of the Bioterrorism Acts of 2002

- The U. S. has determined which facilities possess select agents within the boundaries of the United States.
- The U. S. requires registration and approval of facilities that acquire, use, store, transfer, and dispose of select agents.
- The U. S. approved facilities must provide security of select agents.
- The U. S. requires a background check of persons with access to select agents.
- Technical and Legal Expertise
- The U. S. has compiled lists of technical and legal experts in the area of biosecurity and national implementing efforts to advise the government.
- These lists include experts from both within and outside the United States.

Emergency Response Preparations

- The CDC established a nationwide Laboratory Response Network of laboratories that can identify high-priority agents of bioterrorism.
- The Federal Emergency Management Agency (FEMA) established a network of emergency management agencies in each State in the United States to coordinate response in the event of a biological crisis.

Specific Guidelines for Achieving Adequate Protection

- An interagency committee of the U. S. government, led by the White House Office of Science and Technology Policy and established by the CDC, developed guidelines for security of pathogens that augment the provisions of the Bioterrorism Acts of 2002.
- These guidelines address risk assessment, access control, background checks, and emergency response plans.

Requirements for Safe and Secure Transport of Select Agents

- In response to the Bioterrorism Acts of 2002 rules on safe and secure transport of select agents were revised and augmented.
- These rules define conditions for transfer of select agents between approved facilities.

National Regulatory Bodies

- The CDC, a branch of HHS, is the national body to regulate the security of dangerous human pathogens and toxins.
- The Animal and Plant Health Inspection Service (APHIS) of the Department of Agriculture is the national body to regulate the security of dangerous plant and animal pathogens and toxins.

Maintaining and Monitoring Security of Select Agents

- A United States Government interagency group monitors national activities addressing pathogen security and periodically reviews the list of select agents.

Summary

- The United States recognizes the importance of ensuring the security of dangerous pathogens and toxins and has taken specific measures to reduce the risk of theft or diversion of pathogenic microorganisms and toxins.
- Specific measures to reduce this risk are now being enforced.
- The United States views the actions it has taken as important for national security, but recognizes that the efforts all countries take to ensure the security of dangerous pathogens and toxins contributes to global security as well.
- The United States is happy to share information on the measures it has taken and the lessons learned from those measures with other States Parties of the BWC.

Iran

We underline the importance of the implementation of the Convention on Biological Diversity, the Rio Declaration as well as the Agenda 21 adopted by the United Nations Conference on Environment and Development held in Rio de Janeiro, Brazil; 1992. We welcome the adoption of the Protocol on Biosafety to the Convention on Biological Diversity in 2001. The Islamic Republic of Iran is committed to the aforementioned instruments. We will have more detailed presentations on various topics during the course of the week.

In order to promote the capabilities of the States Parties on biosafety, we encourage the publication, exchange and dissemination of information on research and development on the peaceful uses of microbial or other biological agents and toxins, biosafety, prophylactic and protection, biotechnology, Good Laboratory Practice and current Good Manufacturing Practice, and diagnosis, surveillance, detection, treatment as well as prevention of diseases caused by microbial and other biological agents and toxins.

We are seriously concerned about the existing gap between the developed and developing countries in the security and oversight of the pathogenic microorganisms and toxins, biotechnology, genetic engineering, molecular biology and other related areas.

While applying stringent control on transport and transfer of dangerous pathogens, in order to improve global health, States Parties are expected to actively continue to promote international cooperation and exchange equipment, materials, and scientific and technological information among themselves on the security and oversight of the pathogenic microorganisms and toxins for peaceful uses of biotechnology. We urge States Parties possessing advanced capability on the security and oversight of the pathogenic microorganisms and toxins to adopt positive measures to promote international cooperation, with developing countries, on an equal, transparent manner and non-discriminatory basis for the benefit of all humankind. In this regard we stress that measures be taken to fully implement Article X of the Convention.

We are of the belief that States Parties and the relevant international organizations such as WHO, FAO, OIE, in order to maintain the security and oversight of the pathogenic microorganisms and toxins have to commit themselves, to maintain biosafety to provide, or contribute to training and operation of national and/or international rapid response teams for emergency medical assistance, as well as necessary materials and equipment in any case of outbreak.

We urge States Parties to identify possible types of medical, veterinary, or other assistance, which is necessary for promotion and/or of security and oversight of the pathogenic microorganisms and toxins, that might be available upon the request to provide to the other States Parties.

States Parties to the Convention are expected to avoid hampering the economic and technological development of the States Parties or imposing and maintaining any restrictions incompatible with the obligations undertaken under the Convention. Limitations on the exchange among States Parties for purposes consistent with the objective and provisions of the Convention of scientific knowledge, technology, equipment and materials hampers the spirit of cooperation and jeopardizes the universality.

We emphasize that States Parties to the Convention have a legal obligation to refrain from imposing restrictions or limitation for transfer that would hamper economic or technological development of the States Parties or international cooperation for peaceful applications in the field of biotechnology. Therefore, development of national export regulatory mechanisms should only be undertaken by harmonizing both the promotional and regulatory aspects, vital to sustaining a peaceful development of biotechnology.

China

Statement on Biosecurity and Oversight: Practice and Proposals

With the rapid development of biotechnology and escalation of bioterrorism threats, it has become all the more imperative and important for states to adopt concrete measures to strengthen biosecurity. China attaches great importance to biosecurity and oversight.

I. China's Practice

With regard to legal, regulatory and administrative approaches for ensuring biosecurity and oversight, China strengthened its management through the following regulations:

- According to Law of the People's Republic of China on the Prevention and Control of Infectious Diseases and its Implementation Regulations, China establishes three categories of infectious bacteria and viruses based on toxicity and seriousness of the diseases caused, and strictly administer the using, storing, carrying and shipping of such bacteria and viruses.
- According to the Regulations on Response to Public Health Emergent Incidents, China administrates the quick response to outbreak of serious infectious diseases so as to effectively prevent, contain and eliminate the harmful consequences.
- According to Administrative Measures for Genetically Modified Food Hygiene, Regulations on the Safety Administration of Agricultural Transgenic Living Things, Measures on the Safety Administration of Genetic Engineering, Implementation Measures on the Safety Administration of Agricultural Biological Genetic Engineering, China strengthens hygiene supervision on genetically modified food, safety administration of transgenic living things and genetic engineering with an aim to safeguard the security of humans, animals, plants, microbes and the ecological environment.

With regard to facilities and equipment, personnel and handling, transport and accountability, licensing and accreditation, China formulated the relevant regulations as following:

- According to Regulations on Labor Protection in Workplaces Where Toxic Substances Are Used, China exercises strict safety administration in workplaces where toxic substances are used, including prevention measures, working protection, personnel health monitoring, etc.
- According to General Guidelines on Biological Safety in Microbial and Biological Medical Laboratory, Measures on the Administration of the Prevention and Control of Infectious Severe Acute Respiratory Syndrome, Tentative Measures on the Administration of Infectious Severe Acute Respiratory Syndrome Virus Research Laboratories, China establishes detailed requirements for the administrative mechanism, design criteria and handling guidelines for laboratories of BL2 and above so as to prevent inter-laboratory infection and leaking of pathogenic microorganisms.
- According to Regulations of the People's Republic of China on the Storage and Administration of Microbial Bacteria Species, Measures of the People's Republic of China on the Administration of the Storage of Medical Microbial Bacteria Species, Tentative Measures on the Administration of the Storage of Veterinary Microbial Bacteria Species, Regulations on the Administration of Bacteria, Virus, Insect Species Used in the Production of Veterinary Biological Products, China strictly administers the classification, selection, collection, storage, identification, indexing, supply, use and external exchange of microbial bacteria, virus and pathogenic insect species.

Those mentioned above are China's major laws, regulations and practice in national implementation measures and biosecurity and oversight mechanisms. (for details, see working paper 9---A Compiled List of Laws Regulations of China in Relation to the Implementation of

the Biological Weapons Convention). These laws, regulations and measure have been proven by practice to be effective.

II. China's Perspectives and Proposals

Biosecurity plays an important part in the implementation of the Convention. States Parties should guarantee, through legal and administrative measures, that pathogenic microorganism and toxins be used for peaceful purposes not prohibited by the Convention, and not be used for biological weapon or bioterrorism purposes. At the same time, States Parties should attach importance to safeguarding public health and security.

China holds that risk assessment of microbe should be carried out, physical protection levels, design and operation guidelines of laboratories be established, the wrapping, storage, transfer of pathogenic microorganisms be strictly administered.

- Biosecurity licensing and personnel accreditation systems should be established. Organizations and individuals engaged in biosecurity related R&D activities should be accredited according to the evaluation of qualifications and capabilities. Manuals of Code of Conduct should be formulated for R&D personnel in this field. Operation procedures should be laid out to ensure that risk assessment and practical and effective safety measures be in place before any biosecurity-related research activities start. Violators should be punished accordingly.
- Biosecurity-related knowledge should be popularized. Related personnel should be trained on biosecurity so as to raise their awareness of prevention and capability of accident handling.
- States Parties should cooperate with related international organizations such as WHO and OIE so as to make full use of their resources and achievements. States Parties can discuss and formulate, on the basis of the guidelines of the WHO and OIE, practical biosecurity standards and handling procedures for the reference of all states. Exchanges and cooperation in biosecurity should be promoted, assistance and support be made available to countries in need. States Parties can also make use of the technical expertise of WHO and OIE to establish and improve national biosecurity and oversight mechanism.

Sweden

The Swedish contribution to the discussion concerns the structure of the Swedish legislation on biosafety and cooperation between enforcement authorities within EU. This is a fundament whereupon oversight of biosecurity and confidence building can be further developed.

- International cooperation
- WHO
- Harmonised regulation

International cooperation is vital in the field of biosafety and biosecurity. Most of the existing regulation concerning biosafety is based on WHO guidelines, such as the Biosafety Laboratory Manual, where you can find the criteria for classifying biological agents into 4 risk groups and

laboratory design and practice, suitable for work with each risk group. Practically all regulation around the world is based on this, such as NIH-CDC guidelines in USA and the Swedish work environment regulation, which was in force before 1990, when the first EC Directives in this field were issued. When you compare the description of the Swedish national legislation and authorities to control work with microorganism, you will find that it resembles regulation in many other countries.

- Risk assessment
- Classification of agents, 4 risk groups
- Standard procedures, 4 biosafety levels
- Safe handling and storage

These are the basics for biosafety, worldwide. It is important to have means to make sure that it really works in practice. There is need for legislation, control and oversight.

Control, oversight

- Biosafety –security management, in house self check

The control must start in house. In Sweden, as in many other countries, there is a requirement to have a system for self check within the organisation using the biological agents. The employer (or equivalent) must have a system where there is somebody responsible for biosafety at all levels. This includes to have knowledge about what agents are handled, by whom and how. It also includes to make sure that provisions are followed and implemented. The employer shall see to that the persons allotted these tasks are sufficient in number, have the authority, the resources and the competence that are needed. This system makes it more difficult for persons to perform prohibited work.

- Enforcement authorities

It is not possible for the enforcement authority to be everywhere all the time. This is why the employers system for self check is so important. But there are certain tasks for the authority.

- Notification, permit, inspection

All contained use of GMMs and work with biological agent at biosafety level 2 or higher must be notified or have permit according to Swedish regulation. This gives an opportunity for oversight. Certain information must be given to the authority. Permit is needed for all work with agents class 3 and higher and for class 2 large scale use. It is possible to combine permit with conditions, for example that practical training of contingency plans must take place regularly. The premises can be visited by the authority when handling the application for permit and inspections can be performed at any time to control compliance with the regulation and with conditions stipulated in a permit.

- Cooperation within EU
- Competence building
- Harmonisation
- Confidence building

The regulation concerning biological agent, including genetically modified microorganisms (GMMs) is based on EC Directives. These are minimum Directives and the implementation can vary between Member States. The enforcement Authorities within EU have identified a need for cooperation to share experience, learn from each others and harmonise the enforcement procedures. This has been very useful. Checklists for inspections, discussion groups, joint inspections, web site and e-mail contact etc. have been tools to harmonise our work and get a better understanding of differences.

- Biosecurity adds to biosafety

Biosafety comes before biosecurity. To start with you need classification of agents, standards for safe handling and storage of agents, biosafety management etc. On top of this, certain measures to safeguard biosecurity can be added. In the field of biosafety, cooperation between authorities can build competence as well as promoting understanding and confidence. Examples of possible measures to strengthen this are:

- Network, assistance
- Training of inspectors
- Joint inspections

India

This week we are taking up consideration of national mechanisms to establish and maintain the security and oversight of pathogenic microorganisms and toxins. Just as India has a long history of adopting legislative measures to deal with microorganisms and genetically modified organisms that could have a negative impact, including possible misuse, we also have elaborate rules of procedures and safety guidelines in place for maintaining the security and oversight of such materials. In accordance with the Indian Environment Protection Act of 1986, rules for the manufacture, use/import/export and storage of hazardous microorganisms/genetically engineered organisms or cells were notified in 1989. These rules are applicable to the whole of India in the following cases:

- (a) Sale, offer for sale, storage for the purpose of sale, offers and any kind of handling over with or without a consideration.
- (b) Exportation and importation of genetically engineered cells or organisms.
- (c) Production, manufacturing, processing, storage, import, drawing off, packaging and repackaging of the genetically engineered products.
- (d) Production, manufacture etc. of drugs and pharmaceuticals and food stuffs distilleries and tanneries, etc. which make use of microorganisms/genetically engineered microorganisms one way or the other.

The competent authorities who implement the various provisions are as follows:

- (a) The Recombinant DNA Advisory Committee reviews development in biotechnology at national and international levels and recommends suitable and appropriate safety regulations from time to time. This committee functions in the Department of Biotechnology.
- (b) Institute Biosafety Committees have been constituted in research institutions and industries; Over 230 such committees already exist which review the implementation of programmes from the view point of biosafety.
- (c) Review Committee on Genetic Manipulation functions in the Department of Biotechnology to monitor the safety related aspects in respect of on-going research projects and activities. It brings out manuals of guidelines specifying procedure for regulatory process with respect to all relevant activities. All on-going projects involving high risk category and control field experiments are reviewed to ensure that adequate precautions and containment conditions are followed as per the guidelines.
- (d) Genetic Engineering Approval Committee functions under the Department of Environment and is responsible for approval of proposals relating to release of genetically engineered organisms and products into the environment, including in experimental field trials.
- (e) State Biotechnology Coordination Committee exists in different States of the Indian Union. They have powers to inspect, investigate and take punitive action in case of any violations.
- (f) District Level Committees have been created wherever necessary to monitor the safety regulations in relevant installations.

The Recombinant DNA Safety Guidelines of 1990, revised again in 1994, and a further Revised Guidelines for Research in Transgenic Plants of 1998 and guidelines for generating pre-clinical and clinical data for rDNA vaccines, diagnostics and other biologicals, 1999, deal with genetic transformation of green plants, recombinant DNA technology in vaccine development and on large scale production and deliberate/accidental release of organisms, plants, animals and products derived by such technology into the environment. Appropriate practices, equipment and facilities necessary for safeguards in handling organisms in various risks groups have been recommended. The guidelines provide guidance on containment and safe laboratory practices. They also deal with import and shipment of genetically modified material for research use, covering the entire spectrum of activities related to genetically modified organisms.

What I have attempted is to give you an impression of the various mechanisms already in place along with an idea of the agencies at national, state, district and institutional level which are engaged in enforcing and monitoring the safety requirements. Additional details could be provided by the experts of my delegation.

We look forward to learning from others, realizing that others considerable potential exists for international cooperation and assistance in this field.

Republic of Korea

The Government of the Republic of Korea has enacted diverse provisions related to the safety and security of biological agents and toxins that provide mechanisms and means to strengthen and implement the Convention. The Republic of Korea has three separate agencies responsible for the control and oversight of pathogens. Human pathogens are governed by the National Health Institute under the authority of the Ministry of Health and Welfare. Animal pathogens and plant pathogens, both under the authority of the Ministry of Agriculture and Forestry, are also governed by the National Veterinary Research and Quarantine Service and National Plant Quarantine Service, respectively.

In Korea, the Prevention of Contagious Diseases Act declares the measures related to conservation and management of pathogens of contagious diseases to be one of the duties of State and local governments. A presidential decree and a ministerial decree provide for detailed procedures and standards for the implementation of the Act. The Act requires that if medical institutions, national biomedical institutes or academic research institutions isolate the specific pathogens of contagious diseases, they shall report the relevant information to the National Institute of Health without delay. The specified pathogens comprise 10 types of pathogens of contagious disease including etiological agents of new emerging infectious syndrome. The National Institute of Health may request the reporting institutions to render necessary cooperation for the conservation and management of those isolated pathogens. The Regulation on the Laboratory Diagnosis, Conservation and Management of Pathogens of Contagious Diseases outlines the requirements for safe management with regard to use, disposal and transfer of the specified pathogens.

The Guideline on Recombinant DNA Experiments was developed by the Ministry of Health and Welfare in 1997. It provides a document for the classification system of risk groups and lists of human pathogens according to their hazard and essential elements. It also attempts to define the containment conditions in order to ensure bio-safety in laboratories for genetic modification experiments, while also providing for the establishment of a bio-safety committee and outlining its duties. The Act on Transboundary Movement, etc. of Living Modified Organisms was enacted in 2001.

My delegation would like to underscore the need to increase and strengthen our preparedness against bio-terrorism. As noted with concern in UN Security Council Resolution 1373 (2001), there exists a close connection between international terrorism and the illegal movement of nuclear, chemical, biological and other potentially deadly materials. Thus, it is important that national measures to implement the prohibitions of the Convention be reviewed in accordance with new and emerging security needs and technological developments.

To help ensure full preparedness and an effective response against bio-terrorism in the Republic of Korea, a revision of the Prevention of Contagious Diseases Act that designates an outbreak of disease by intentional use of pathogens, such as in the case of bio-terrorism, is currently under review in the National Assembly. The new provisions that consolidate and strengthen the governmental oversight mechanism for pathogens of contagious diseases are also being considered. The Act for Prevention of Livestock Epidemics provides for similar duties and procedures for pathogens of infectious livestock diseases.

To ensure the safe transport and transfer of biological agents and toxins, a thorough notification system must be established. Such a system should include essential categories such as types and quantities of agents, relevant information about the consignor/consignee, information on the sites where agents are to be introduced, methods of transportation and containment measures applied thereto.

We believe that extensive cooperation between inter-governmental agencies and international export control regimes is an important element in maintaining effective export control. In the ROK, an inter-agency consultative meeting is held at the request of any Ministry in charge of export control to review all related matters. Moreover, the Public Notice on the Export and Import of Strategic Commodities, which incorporates the obligations pursuant to Article IV of the BWC, maintains controlled lists of materials, equipment and technologies. The coverage of items subject to export control under the Public Notice has been expanded to include items currently controlled by the NSG, MTCR and AG. Because the Korean Government attaches great importance to export control as a practical means of non-proliferation of WMD, including biological and toxin agents, the ROK will do its utmost to further reinforce its domestic export control system by actively joining the international efforts to make the export control regime more efficient and effective.

With regard to import control, the Quarantine Act ensures that the import of specified pathogens shall not be permitted for quarantine procedures without advanced permission by the Minister of Health and Welfare. The Act for Prevention of Livestock Epidemics and the Plant Protection Act provide that pathogens of animal diseases and plant diseases, respectively, shall not be imported except in the case of research and experiments granted prior approval.

In concluding, we would like to note that the efficacy of those national measures of legislative, administrative or regulatory nature adopted to implement the prohibitions of the Convention should be enhanced through effective oversight. Promoting awareness of the Convention and maintaining regular training in this field is essential to ensuring that the prohibitions and regulations of the Convention are enforced on a day-to-day basis. As oversight of the nature and purpose of activities in this field is essential to maintaining the effectiveness of national measures, efforts should be made to ensure that the national legislation and regulations are reviewed on a regular basis. Reiterating that the adoption and subsequent implementation of national measures by States Parties are essential to the effective implementation of the Convention, we continue to encourage all States Parties to ensure national implementation of the prohibitions contained in the Convention.

Brazil

In Brazil, two Laws are at the core of our body of legislation concerning the control and oversight of pathogenic microorganisms and toxins. Law 8974 of 1995 establishes safety norms and supervision mechanism for, inter alia, genetic engineering activities and techniques, as well as for the release, marketing, consumption and disposal of genetically modified organisms, with a view to protecting human, animal, and plant health, as well as the environment. This Law also established the National Technical Committee on Biosafety (CTNBio). Provisional Decree 2186-16 of 2001, in turn, regulates relevant paragraphs of Article 225 of the Constitution, concerning Articles 1 and 8 of the CBD, with a view to establishing rules for access to genetic patrimony and its associated traditional knowledge in Brazil, so as to ensure a fair distribution of

benefits and to regulate associated technology transfer. Furthermore, this Law absolutely prohibits access to any element of the Brazilian genetic patrimony or its use in connection with the production of chemical or biological weapons.

We consider that during the first week of the meeting of experts we were able to exchange valuable information concerning domestic legislation relating to the prohibitions of the BWC. At the start of the discussion of item 6 of our agenda, we would like to point out our positive expectations about the usefulness of the results of our meeting for the meeting of States Parties.

In this connection, we would like to recall that our discussion should not lose sight of the fact that the topics we discussed last week and the ones we will consider in the next few days are closely related to the objectives of the Convention as a whole.

This may be illustrated by the discussions we had last week on the necessary balance between restrictive measures to ensure the implementation of the BWC's prohibitions, on one hand, and, inter alia, the right to develop biotechnology as a tool for national development and exclusively for peaceful ends, on the other.

In this connection, and in line with our working paper BWC/MSP.2003/MX/WP.20, we would like to point out that the following aspects, which were also mentioned by other delegations today, should be given due consideration in our discussions:

- core needs and missions of BWC National Authorities, or their functional equivalents clearly identified and legally empowered;
- the need to define national lists or criteria for pathogenic microorganisms and toxins and critical equipment subject to control and a flexible mechanism to update those lists and criteria domestically and exchange information on them internationally (much in the way computer virus vaccines are updated);
- establishment of national mechanisms to monitor and oversee the enforcement of legislation by the appropriate national law-enforcement bodies on biosecurity of facilities (production, possession, acquisition, stockpiling), and of transport of specified pathogenic microorganisms and toxins and critical equipment;
- establishing and maintaining import/export controls according to national legislation and regulations, including licensing of international carriers;
- monitoring potentially dangerous activities involving specified pathogenic microorganisms or toxins and critical equipment (including research, development, production, stockpiling, and transfers);
- establishing a mechanism for interaction among National Authorities or their functional equivalents;
- conducting national assessments, on a continuing basis, on the effectiveness of the relevant domestic legislation for use in recommendations to the respective national government;
- the need to establish elements for a common understanding on a BWC mechanism to oversee the implementation of national measures, and to assist in resolving ambiguities and to promote international collaboration in cases of suspicious unlawful activities.

Cuba

Como es conocido, uno de los sectores que ha venido desarrollando Cuba con carácter prioritario es el de la biotecnología. Nuestro país dedica importante recursos y esfuerzos a este sector, como resultado de los cuales hoy Cuba muestra índices muy altos de desarrollo en esta esfera.

Ello implica que en Cuba un número relativamente importante de instalaciones y personas manejan, de una manera u otra, microorganismos y equipos de alta tecnología, por lo que se ha establecido un riguroso mecanismo nacional para garantizar la seguridad de esos agentes y equipos.

Como parte de ese mecanismo de bioseguridad, en Cuba se ha adoptado y se implementa rigurosamente, un amplio conjunto de legislaciones y regulaciones.

Las delegaciones interesadas en conocer más detalles sobre estas legislaciones y regulaciones, pueden consultar el documento de trabajo que ha presentado Cuba bajo el tema 6. En esta ocasión, nuestra delegación hará una intervención breve para dar una panorámica general de la legislación cubana en materia de bioseguridad.

En Cuba las medidas para la protección de los agentes biológicos y toxinas están enmarcadas en la legislación de bioseguridad y abarcan las esferas de la salud humana, animal, vegetal y el medio ambiente.

Fuentes de legislación cubana sobre bioseguridad.

El desarrollo de los documentos regulatorios cubanos esta basado en los documentos elaborados por los organismo internacionales como la OMS, la FAO, la OIE y el PNUMA, así como se han tenido en cuenta la experiencia nacionales de otros países.

Registro de Instalaciones.

Desde 1997 se ha desarrollado en nuestro país una encuesta nacional de seguridad biológica con el fin de conocer la cantidad de instalaciones que manipulaban agentes biológicos, poseían equipos y sistemas de seguridad así como el desarrollo en cuanto a la aplicación de las medidas de bioseguridad. Esta encuesta tuvo una aplicación nacional.

Más reciente, el Reglamento de Contabilidad y Control de Materiales biológicos, equipos y tecnologías aplicados a estos, en fase de aprobación por el Ministerio de Ciencia, Tecnología y Medio Ambiente, establece un registro para aquellas entidades que realizan las siguientes actividades:

- a) Producción de vacunas para uso humano.
- b) Producción de vacunas para uso veterinario.
- c) Producción de Bioplaguicidas y Biofertilizantes.
- d) Uso de los materiales biológicos listados en el anexo uno (1) que forma parte integrante del presente Reglamento.
- e) Uso de los siguientes equipos:
 - 1. Cámaras de aerosoles estáticas, dinámicas o explosivas.
 - 2. Equipos para generar aerosoles de microorganismos o toxinas y simulantes.

3. Gabinetes de Seguridad Biológica clase III o clase I convertible a III.
 4. Aislante de película flexible u otras cámaras equivalentes a clase III y caja anaeróbica.
- f) Trabajo con inoculantes para plantas.
- g) Modificaciones genéticas.
- h) Transferencia de tecnología que involucre la realización de las actividades mencionadas en los incisos anteriores.

Además de las entidades a que se refiere el apartado anterior, deben ser registradas aquellas que cuentan con instalaciones de niveles de seguridad biológica tres (III) y cuatro (IV) y las que realicen actividades correspondientes a cualquier nueva tecnología o conocimiento científico.

Las cuales deberán rendir informes semestrales y anuales sobre sus actividades, están sujetas a licencias e inspecciones periódicas.

Marco Legal

La legislación cubana cuenta en la actualidad con 5 documentos vigentes, un Decreto Ley y 4 resoluciones, así como dos resoluciones en fase de aprobación.

Los 5 documentos vigentes, los cuales se detallan en el documento de trabajo presentado por nuestra delegación y en los dos CD entregados a la secretaria, se regulan los siguientes tópicos:

- Principios generales de la Bioseguridad.
- Clasificación de los agentes biológicos en grupos de riesgo.
- Clasificación de las Instalaciones según los niveles de bioseguridad.
- El transporte de sustancias infecciosas.
- Los procedimientos de emergencias.
- Las autorizaciones de seguridad biológica.
- Los requisitos para el diseño y construcción de las instalaciones con riesgo biológico.
- Los equipos de seguridad.
- Las prácticas y procedimientos apropiados.

Además se trabaja en el perfeccionamiento del sistema de inspecciones, el sistema de verificación de las barreras de contención, el sistema de regulación, el programa de información al público, la capacitación, entre otros elementos relacionados con la temática.

El órgano regulador de la Bioseguridad.

En Cuba las actividades relacionadas con la seguridad biológica, se comienzan a organizar desde 1984, con la creación por la entonces Academia de Ciencias, de una Comisión de Bioseguridad. Los trabajos organizativos en esta esfera cobran fortaleza en 1992 y adquieren carácter institucional en 1993, al designarse a la extinta Comisión Nacional de Protección del Medio Ambiente y del Uso Racional de los Recursos Naturales (COMARNA), como entidad encargada de proponer al Estado y al Gobierno la política a seguir en esta materia.

Lo anterior, unido a la existencia de los documentos jurídicos internacionales, como el Convenio de Diversidad Biológica, El Protocolo de Cartagena y la Convención de Armas Biológicas, conlleva a la impostergable decisión de crear una estructura que, a nivel nacional, brinde especial atención a los problemas de la bioseguridad. Es en este contexto que se emite por la Ministra de

Ciencia, Tecnología y Medio Ambiente la Resolución No. 67 en 1996, disponiendo la creación del Centro Nacional de Seguridad Biológica (CNSB), con funciones muy específicas en este campo. En su condición de órgano regulador, dicho Centro se ocupa, entre otros aspectos, de:

- Elaborar documentos regulatorios y normas técnicas sobre bioseguridad.
- Otorgamiento de Autorizaciones de Seguridad Biológica, las cuales incluyen: Licencias, Permisos y Notificaciones.
- Ejecutar las inspecciones de Seguridad Biológica.
- Velar por el cumplimiento de los compromisos contraídos por Cuba, como Estado Parte ante Tratados y Convenios relacionados con la Bioseguridad.
- Capacitación y superación profesional en Bioseguridad

En resumen, estas son algunas de las principales medidas tomadas por Cuba para la protección de los agentes biológicos y toxinas. En otras presentaciones hablaremos sobre el Sistema de Inspecciones y Autorizaciones de Seguridad Biológica.

(informal transcript of the English interpretation)

In the case of Cuba one of the sectors that has been most developed as a priority is biotechnology, and this means that Cuba has a large number of persons directly managing microorganisms, toxins and very high-level technology. And thus, Cuba has had to set-up a very rigorous national mechanism to ensure the security of these agents and equipment.

In the framework of this biosecurity mechanism in Cuba we have adopted a large number of laws and regulations that take into account the biosecurity directive of the international organizations such as the WHO, FAO, and others and we have adapted these conditions in Cuba. I would now like to give the floor to my colleague, Mr. Mantas, who represents the National Centre for Biosecurity in Cuba.

This center is the regulatory body in Cuba for all issues of biosecurity, and my colleague would like to give a general presentation of the legislation in Cuba in this field. I recall that Cuba has already presented to the Secretariat a Working Paper on the issue and we hope that it will be rapidly made available to you so that all delegations that have an interest in this can consult it. Without further delay, I will thus give the floor to the representative of the National Centre for Biosecurity. Thank you.

In Cuba the measures for the protection of bioagents and toxins, for plant health and the protection of the environment, the improvement of the regulations is based on documents prepared by international bodies such as WHO, FAO, OIE and the UNEP. We have also taken account of the national experience of other States.

As regards the register of installations in our country since 1997 we have had a national questionnaire on biosecurity and also know the number of installations working with bioagents which have security systems and the application of biosecurity measures. This questionnaire has been carried throughout the country.

More recently the regulation on control of biological agents, equipment and technology which is on the virtue of being approved by the Ministry of Technology and Environment provides for a

register for all bodies working in the following fields: production of human and veterinary vaccines, production of fertilizers, biological materials in an Annex A under the regulation.

Use of the following equipment: aerosol chambers, aerodynamics, equipment for microorganisms for toxins and other, security chambers for biological matters (class 3), work for inoculation of plants, genetic transfer and modification technology. Of the bodies that have been referred to already they are registered including those which have level 3 or 4 biological activities and those carrying out activities of high technological level.

These installations provide annual reports on their activities, and are periodically inspected and licensed. As regards the legal framework the legislation in Cuba is currently based on 5 documents: One decree law and four resolutions as well as two draft resolutions. The five documents, these five instruments which are listed in the working document presented by our delegation and in the document provided to the Secretariat are in following fields:

- General principles of biosecurity;
- Classification of biological agents into risk groups;
- Classification of installations according to level of biosecurity;
- Transport of infectious substances;
- Emergency procedures;
- Authorization in biological security matters;
- Provisions for the construction of biological risk installations;
- Safety equipment; and
- Practice and procedures at the appropriate level.

There is also work being carried out to improve the inspection system, the control system for application of the rules, the regulatory procedures, the information programme, training, and other matters.

In Cuba, there is a regulatory body for biosecurity since 1996. Resolution 1 of the Ministry of Technology and the Environment has specific functions within this Resolution as follows: It is a regulatory document and establishes technical norms for biosecurity to supervise the licensing permits and notifications to implement norms in biosecurity and to ensure the international commitments as Cuba as a States Party to biosecurity instruments, ensure training in biosecurity. And in general, these are the activities carried out in Cuba in a following statement we will speak of authorisations in the field of biosecurity.

Japan

Some measures to enhance biosafety/biosecurity in Japan

The Laboratory Safety Regulation for Biological Agents of the National Institute of Infectious Diseases, a leading organization in the field of biosafety in Japan, has been referred to widely by other research institutes, business enterprises and universities in Japan as a model for biosafety management guidelines. It has been revised several times, taking into account the WHO Laboratory Safety Manual and biosafety systems in other countries. The Regulation includes a list of pathogens to be controlled and, following broad classification depending on a suitable host (human or animal), the list divides pathogens into four biohazard levels. The Regulation also

prescribes such matters as safety standards for equipment and management of laboratories, measures to be taken in emergencies, health care and safety management training of personnel handling biological agents.

Concerning the recombinant DNA experiments, the Guidelines for Recombinant DNA Experiments has been established by the Ministry of Education, Culture, Sports, Science and Technology. The Guidelines contain detailed requirements for various matters, including containment methods and equipment, handling of GMO including shipment and disposal after experiments, health care and training of personnel who conduct experiments. The Guidelines require notice or prior approval by the institutional biosafety committee. Certain types of experiments require confirmation by the Ministry of Education, Culture, Sports, Science and Technology.

In addition, there are separate guidelines for the safe use of DNA recombinants in the industry and in the field of agriculture, forestry and fishery. Both guidelines prescribe detailed requirements for safety handling procedure of DNA recombinants in the facility. Screening for actual use of such recombinants can be individually performed by the Ministry of Economy, Trade and Industry or the Minister of Agriculture, Forestry and Fisheries when requested.

Libyan Arab Jamahiriya

التدابير الخاصة بتنفيذ اتفاقية حظر الأسلحة البيولوجية والمواد السامة

ضمن النظام القانوني في الجماهيرية العظمى

تؤكد الدراسات المتخصصة في المجالات الطبية والزراعية والهندسية أهمية المواد الكيميائية والوسائل والتقنيات البيولوجية وتعتبر من ضروريات الحياة اليومية فهي توفر فوائد كبيرة ودعمًا للمجتمعات النامية والمتقدمة على حد سواء فهي تدخل في معظم العمليات الصناعية وتدعم قطاع الزراعة كما أنها تساهم في توفير المستلزمات الضرورية لقطاع الصحة من خلال توفير الأدوية والأمصال ومختلف أنواع العلاج التي لا بد منها في صراع البشر للقضاء على المرض ووقاية الصحة والإسهام في مجالات حماية البيئة ، إلا إن هذه المواد والوسائل والتقنيات في الواقع العملي المعاش لم يقتصر استخدامها في الأغراض السلمية التي سبق ذكرها فقط بل تم استعمالها وبصورة بشعة في إذكاء نار الحروب وبالتالي الفتك بالملايين من البشر وسائر المخلوقات ومن هنا يمكن القول بأن الأبحاث الكيميائية والبيولوجية تمثل سلاح ذو حدين فهي مفيدة ونافعة إذا أحسن استعمالها وضارة ومدمرة إذا أسئ استخدامها هذه الازدواجية الصعبة خلقت نوعاً من الصراع الذي ساد الأوساط العالمية واستمر هذا الصراع بين قوى الخير وشراذم الشر إلى أن قامت الحرب العالمية الأولى .

* الحاجة الماسة لتنظيم استعمال المواد الكيميائية والبيولوجية والمواد السامة والخطرة على المستوى الدولي :-

نظراً للانتشار الكبير الذي شهدته الاستخدامات المختلفة للأبحاث الكيميائية والبيولوجية في المجال الصناعي والتوسع في استعمالها كمبيدات في المجال البيئي والمجال الزراعي بصورة خاصة وإدخالها كذلك في حالات النزاع المسلح والحروب المختلفة بالشكل الذي جعل من كل خصم في النزاعات المسلحة يبدل قصارى الجهد في سبيل الحصول على الأسلحة التي تقوم على الأبحاث الكيميائية والبيولوجية أن لم يتمكن من تصنيعها وذلك لسرعة تأثيرها في كسب المعارك وحسم الخلافات الأمر الذي أدى إلى ظهور الكثير من المشاكل البيئية والصحية في معظم دول العالم . ونتيجة لذلك فقد قامت الشعوب ممثلة في الهيئات والمؤسسات العلمية والمنظمات غير الحكومية والجمعيات الأهلية بالبحث عن وسائل قانونية ومادية للحد من إنتاج الأسلحة الكيميائية والبيولوجية ومنع انتشارها بكافة السبل والوسائل وكان من نتائج هذه الجهود المضنية أن ظهرت إلى حيز الوجود العديد من الاتفاقيات والمعاهدات الدولية التي تلزم الدول المنضمة إليها بالعمل على تدمير الأسلحة التي تمتلكها والعمل على منع إجراء تجارب جديدة في هذا المجال وعدم نقل تلك التقنية الوحشية لدول أخرى والسماح بإعادة استخدام الأبحاث التي تم التوصل إليها في الأغراض السلمية كنوع من التعويض للدول التي تكبدت دفع الأموال الباهظة في سباق الشر ، وتشجيعاً لتلك الدول ولغيرها على المشاركة في سباق من نوع

التقنيات والوسائل البيولوجية في الأغراض السلمية المسموح بها وفقاً لأحكام الاتفاقية المشار إليها وأثناء كل مرحلة من مراحل الاستخدام مثل مراحل استجلاب المواد من مصادرها الخارجية للمصانع والمعامل الطبية ومراحل التصنيع والتخزين والتداول..... الخ ، نجد أن النظام القانوني الليبي أقر العديد من القوانين واللوائح والنظم الإدارية المتعلقة بمنع استخدام المواد الخطور استخدامها ووضع الوسائل القانونية اللازمة لردع المخالفين كما أقر غيرها من النصوص القانونية التي تقنن الاستخدام المسموح به للأغراض السلمية ونذكر هنا بعض النماذج لتلك القوانين والقرارات التي صدرت في هذا الصدد وذلك على النحو التالي :

المرحلة الأولى : القوانين والقرارات الصادرة قبل الانضمام للاتفاقية :

خلال هذه المرحلة صدرت العديد من القوانين والقرارات التي تنظم الاستخدام السلمي للمواد الكيميائية والوسائل البيولوجية والمواد السامة والخطرة التي يمكن أن تستخدم للأغراض الطبية ومن المأخذ على هذه القوانين والقرارات أنها لم تكن قوانين متخصصة تركز على مسألة بعينها بل كانت عامة تتضمن علاج المسائل الكيميائية والبيولوجية والمواد السامة مجتمعة في نص أو أكثر ولعل هذا الحال ينطبق على بروتوكول جنيف الذي سبق أن نوهنا على أنه عاجل المسائلتين في آن واحد ثم فصل بين المجالين ضمن معاهدين منفصلتين . ونذكر من هذه القوانين واللوائح على سبيل المثال لا الحصر :-

القوانين والقرارات المتعلقة بقطاع الزراعة :

• القانون رقم (27) لسنة 1968 ف لوقاية النباتات: أكد هذا القانون إن للجماهيرية تجربة عريقة في مجال وضع التشريعات الخاصة بتحريم امتلاك واستعمال المواد الكيميائية والوسائل البيولوجية والمواد السامة والخطرة وهذا ما يتضح من خلال الاطلاع على الفصل الثالث من القانون وبالتحديد المواد (7 ، 8 ، 9) فنجد مثلاً المادة (7) من القانون المشار إليه تتضمن النص على مبدأ عدم جواز التعامل في المبيدات الكيميائية ومشتقاتها بصناعاً أو إنتاجها أو استيرادها أو الاتجار فيها إلا بعد الحصول على إذن بذلك من إدارة وقاية النباتات التابعة لقطاع الزراعة آنذاك . وتضمنت الفقرة الثانية من نفس المادة النص على ضرورة قيام الجهة المختصة بإصدار الأذن بالاستخدام المسموح به بفتح سجل لقيد المتعاملين في المبيدات الزراعية كما ألزم المتعامل المأذون له بالتعامل في المبيدات بمسك سجل خاص به يقيّد فيه البيانات الضرورية عن المواد التي يستخدمها . وأحال القانون على اللائحة التنفيذية بالنسبة لإجراءات إصدار الأذن الخاص بالاستعمال وكذلك الحال بالنسبة للسجل المطلوب فتحة لقيد المتعاملين والبيانات المطلوب إدراجها بالسجل الفرعي الذي يلزم المتعامل في المبيدات الكيميائية بمسكه

**** القرار رقم (740) لسنة 1973 ف الصادر بشأن تحديد إجراءات التعامل في المبيدات الكيميائية الزراعية**
 وتم بموجب هذا القرار إعطاء صلاحية الأذن بالاستيراد بالنسبة للمبيدات الزراعية التي تعتمد في إنتاجها على
 المواد الكيميائية لقسم وقاية النبات بقطاع الزراعة .

***** القرار رقم (460) لسنة 1977 ف وتضمن هذا القرار** تخويل الجهات العلمية الوطنية أعداد دراستها
 حول المبيدات وتحديد فاعليتها ومتطلباتها وسميتها وتسجيل المبيد بعد ثبوت صلاحيته ويؤكد هذا القرار مواكبة
 النظام القانوني الليبي للتطور العلمي في مجال التحذير من النتائج الخطيرة للاستخدامات المختلفة للمواد الكيميائية
 والمواد الخطرة ويطلب القرار من المؤسسات العلمية تحديد درجة السمية للمواد حتى وأن كان استخدامها
 لأغراض ضرورية تتمثل في زيادة القدرة الإنتاجية للمزروعات أو لمكافحة الآفات الزراعية .

****** قرار رقم (461) لسنة 1977 ف الصادر بشأن المبيدات الكيميائية المستعملة في الأغراض الزراعية وأكد**
 هذا القرار على ضرورة قيام الجهات المتعاملة في مجال المبيدات بأجراء تصنيف للمبيدات حسب درجة سميتها
 للإنسان والحيوان والأشخاص المصرح لهم بالاستعمال .

القوانين والقرارات المتعلقة بالقطاع الصحي :

• القانون رقم (106) لسنة 1973 ف الصادر بشأن القانون الصحي :
 تناول هذا القانون العديد من المسائل التي لها علاقة بالحماية القانونية للاستعمالات السلمية للوسائل البيولوجية
 في المجالات الطبية فنجد مثلا تقنين مسألة مزاوله مهنة الأبحاث والفحوص في مجالات الكيمياء الطبية
 والبكتريولوجيا والبالوجيا حيث جاء في نص المادة (121) من القانون المشار إليه بأنه : " لا يجوز لأحد مزاوله
 مهنة الأبحاث والفحوص العملية (الكيمياء الطبية و البكتريولوجيا والبالوجيا) إلا إذا كان طبيياً حاصلًا على
 مؤهل عال في مجال الأبحاث والفحوص العملية " وهذا النص يؤكد أهمية وجود شروط دقيقة لتولي لتولى
 الأعمال ذات الطبيعة الخاصة وذلك للحيلولة دون إساءة استعمالها في الأغراض غير المخصصة لها .
 وتضمنت الفقرة الثانية من نفس المادة حصر الأبحاث والفحوص المقصودة بالخطاب القانوني الوارد بالفقرة
 الأولى بحيث يعتبر مزاوله لمهنة الأبحاث والفحوص العملية القيام بالأعمال التالية :

- (1) الأبحاث والتحليل والاختبارات في ميدان الكيمياء الطبية .
 - (2) الأبحاث والتحليل والاختبارات المتعلقة بالجراثيم (البكتريولوجيا) .
 - (3) الأبحاث والتحليل والاختبارات الخاصة بعلم الأمراض (الباثولوجيا) .
 - (4) تحضير اللقاحات والأمصال والمستحضرات الحيوية .
- ويتضح من خلال النص اهتمام النظام القانوني الليبي بمسألة حماية المهن ذات الطبيعة الخاصة من أن يدخلها غير
 المؤهلين تأهيل يتناسب مع خطورتها وبالتالي يضمن عدم العبث بالوسائل المسموح باستخدامها في تلك المهن .

وتضمن القانون الصحي في مواده (122 ، 123 ، 124 ، 125) معالجة مسائل القيام بالوظائف المكملة للعمل الطبي ومن بينها الوظائف التي تتعلق بالمختبرات الطبية وحدد الشروط اللازمة لشغل هذه الوظائف ووضع الضوابط اللازمة لضمان عدم الانحراف بالعمل في المختبرات الطبية بحيث تستمر في تحقيق الأهداف التي يرسمها المجتمع ولا يسمح باستغلالها في أغراض أخرى محظورة أو لا تتوافق مع الأغراض الإنسانية .

أما المادة (132) من القانون الصحي المشار إليه فقد عاجلت مسألة أخرى من المسائل ذات العلاقة بأهداف الاتفاقية وتمثل في منع تداول المواد السامة والخطرة بصورة عامة وتقنين الاستعمال السلمي المسموح به بحيث تضمنت النص على : معاقبة كل من اتجر في المواد الطبية بما فيها المواد السامة أو الخطرة أو صنعها أو خزنها أو حازها بدون الحصول على الترخيص الذي يتطلبه القانون .

وتجدر الملاحظة أن القوانين والقرارات المشار إليها أعلاه والسابقة في الصدور عن عام (1982) وهو التاريخ الذي انضمت فيه الجماهيرية للاتفاقية قامت بتقنين وتنظيم الاستخدامات المختلفة للمواد الكيميائية والوسائل والتقنيات البيولوجية والمواد السامة والخطرة وتميز طابع العلاج بمنع وتحريم استخدام المواد والوسائل والتقنيات التي تعتمد على الأبحاث الكيميائية والبيولوجية وتلك التي تستخدم المواد السامة والخطرة وذلك لما تسببه من أضرار فادحة للإنسان والبيئة دون الإشارة إلى الاستعمالات التي لا توجد في الجماهيرية أصلاً . وحتى في إطار الاستخدامات السلمية لتلك المواد والوسائل والتقنيات لم تعالج القوانين والنظم الإدارية الليبية إلا ما توفر منها في الواقع وارتبط بخطط الدولة التنموية والتي اقتضت على محاولة الرفع من مستوى الإنتاج الزراعي وتحسين الخدمات الصحية .

القوانين واللوائح والقرارات الصادرة بعد الانضمام للاتفاقية :

(أ) قانون حماية البيئة رقم (7 لسنة 1982 ف) ولائحته التنفيذية :

في سنة 1982 ف صدر القانون رقم (7) بشأن حماية البيئة والذي تضمن في مواده (50 / 51 / 52 /

57) وضع العديد من الضوابط والشروط لتقنين وضبط الاستخدامات المختلفة للمواد والوسائل والتقنيات البيولوجية والمواد السامة والخطرة وذلك على النحو التالي :

- مراقبة استيراد وتصنيع ونقل واستعمال كافة أنواع المبيدات والمواد الكيماوية وبقية المواد الأخرى بما يضمن عدم تلويث مصادر المياه (م 50) . وجلى من هذا النص اهتمام المشرع الليبي بمسألة مراقبة المواد والوسائل الكيميائية والوسائل البيولوجية والمواد السامة والخطرة من خلال وضع جهة تتولى الرقابة الصارمة على استيراد تلك المواد والوسائل وتصنيعها وتداولها وقدم المشرع مسألة استيرادها عن غيرها نظراً لافتقار الجماهيرية لهذه الأنواع من التقنية واعتمادها على استيرادها من الخارج لاستخدامها في المجالات الطبية والزراعية
- تحديد درجة تأثير السموم من خلال بقايا المبيدات الزراعية التي تم استخدامها (م 51)

- تقنين وتنظيم تداول وبيع المواد الخطرة والسامة والمبيدات الكيماوية ومراقبة تأثير المخلفات الصلبة والسائلة على البيئة الزراعية والحياة البشرية والمحيط بصورة عامة (م 57) .

(ب) القانون رقم (15) لسنة 1371 و.ر الصادر بشأن حماية البيئة وتحسينها :

- أصدرت المؤتمرات الشعبية الأساسية القانون المشار إليه لمواكبة التطورات الدولية في مجال تحقيق الحماية القانونية للبيئة بكافة عناصرها وبالصورة التي تواكب التقدم التقني والتطور التشريعي الذي يشهده العالم وهو يدشن القرن الحادي والعشرون .
- وتضمن القانون علاج لبعض أوجه الخلل في القانون رقم (7) لسنة (1982ف) الذي مر على صدوره أكثر من عشرين عاما ومن أهم الأحكام التي وردت طية هذا القانون الجديد والتي لها علاقة بشأن التعامل بالوسائل والتقنيات الخاصة بالمجال البيولوجي والتعامل في بعض المواد التي ينتج عنها سموم ومواد خطرة أخرى للأغراض السلمية وبالتالي لها علاقة بالمعاهدة الخاصة بحظر استحداث وإنتاج الأسلحة البيولوجية (البكتريولوجية) والتكسينية والأحكام هي :-
- (1) اشتراط الحصول الأذن بالإفراج عن منتجات التقنية الحيوية المراد استخدامها بعد التأكد من عدم إضرارها بالبيئة وحماية مستقبل البذور والسلالات الوطنية . (م 10/6)
- (2) ضرورة تقييم الأخطار والآثار المحتملة لاستخدام البذور والسلالات المحسنة جيداً والمعالجة عن طريق الهندسة الوراثية قبل دخولها للجماهيرية العظمى . (م 6 / 19) .
- (3) عدم جواز نقل المواد الخطرة أو التي ينتج عنها أثناء نقلها انبعاث للغبار أو الجزيئات الدقيقة أو الأبخرة إلى الهواء بما يؤدي إلى تلوث البيئة أو الإضرار بالصحة العامة ما لم يتم تغطيتها بأحكام أثناء النقل ووضع علامات وإرشادات السلامة الدالة على درجة خطورة المادة المحملة . (م 1/15) .
- (4) عدم السماح بترك المواد العضوية سريعة التبخر وكذلك المذيبات والأحماض بطريقة تسبب تلوث الهواء الجوي دون تغطيتها بغطية محكمة تمنع تسربها إلى الهواء الجوي . كما لا يجوز التخلص من هذه المواد بأية طريقة كانت إلا وفقاً للشروط والقواعد العلمية التي تحددها الجهة المختصة . (2/15)
- (5) منع استخدام المواد السامة أو أية وسيلة أخرى تضر بالكائنات البحرية عند القيام بأعمال الصيد ودون تميز
- (6) منع حيازة واستعمال أي مادة أو طعم سام قد يعفن أو يسمم أي نوع من الأحياء البحرية . (م 18)
- (7) منع القيام بإلقاء أي مادة أو طعم سام في مياه البحر . (م 18)
- (8) يحظر إلقاء النفايات المواد السامة أو المخلفات في الشواطئ والمياه الإقليمية للجماهيرية (م 33)
- (9) يحظر إلقاء المواد المشعة والخطرة والغازات السامة وكذلك المفرقات وأية نفايات صناعية أو نووية بقصد التخلص منها أو تخزينها في المياه الإقليمية للجماهيرية العظمى (م 35) .
- (10) ضرورة تحديد درجة التسمم الناتجة عن وجود بقايا المبيدات الكيماوية والمواد الأخرى المستخدمة في وقاية النباتات والحضر وأثارها على المنتجات الزراعية .

(11) إلزام الجهات ذات العلاقة بالقيام بالتحليل المخبري المستمر للمواد الغذائية بهدف حماية الإنسان والحيوان والنباتات من خطورة استعمال المبيدات الكيميائية ومن التسمم بالفطريات مع مراقبة المواد الغذائية والأعلاف المصنعة لتحديد نسبة التلوث فيها .

الاستخدامات السلمية للتقنية الحيوية وموقف قانون البيئة الجديد منها :

يمكن القول بأن القانون رقم (15 لسنة 1371 و.ر) الصادر بشأن حماية البيئة وتحسينها تضمن العديد من الأحكام خاصة بمسألة الاستخدامات السلمية للتقنية الحيوية ووردت تلك الأحكام ضمن الفصل العاشر بمواده الستة وذلك على النحو التالي :

(أ) بدأ المشرع بإبراز الخطورة الناجمة عن استخدام كل البذور والسلالات الخورة جينياً والمعالجة بالهندسة الوراثية بالنسبة للبيئة حيث جاء في النص بأنه : " تعتبر كل البذور " (م 58)
(ب) يمنع إدخال أو استيراد أو بيع الكائنات الخورة أو استخدامها كأغذية أو أعلاف أو التعامل فيها بأية طريقة كانت إلا بأذن الجهة المختصة (م 59)

(ج). لا يسمح باستخدام المعزول للنتائج (م 60 .)

(د) إلزام الجهات التي لها علاقة بالتعامل بنتائج التقنية الحيوية بوضع خطة للطوارئ وهذا ما نصت عليه المادة (61) من القانون الجديد حيث جاء فيها : " على الجهات التي يصرح لها من قبل الجهة المختصة بالتعامل مع نتائج التقنية الحيوية أن تقوم بإعداد خطة للطوارئ لتلافي أية أضرار قد تحصل بسبب التعامل مع منتجات التقنية الحيوية واتخاذ التحولات للاستخدام الأمثل والرشد لهذه المنتجات ومعالجة ما قد يطرأ عن استخدامها " (هـ) منع القانون في المادة (62) منه منع استيراد أو حيازة أو بيع أو استخدام منتجات التقنية الحيوية غير المرخص باستيرادها من الجهة المختصة ، وفي جميع الأحوال يجب استعمال الوسائل والتقنيات والمعدات المتوفرة للتقنية للإقلال من الاستهلاك والتلوث ، سواء تمثل الاستهلاك في المياه أو المواد الخام أو الطاقة أو الهواء أو الفراغ أو أي استعمال آخر للبيئة .

الخصائص البارزة في أحكام الحماية القانونية للاستخدامات الوسائل والتقنيات البيولوجية
للأغراض السلمية في النظام القانوني الليبي

من خلال استعراض التشريعات الليبية الصادرة في هذا المجال اتضح أنها تتميز بالعديد من الخصائص نذكر منها على سبيل المثال لا الحصر الآتي :

(*) قيام المشرع الليبي بمراعاة الجانب الإيجابي الذي يستهدف وضع التدابير الاحترازية والنظم الوقائية لمنع استخدام المواد والوسائل والتقنيات التي لها علاقة بالاستعمال المخطور للمواد البيولوجية والمواد السامة والخطيرة وكان من نتائج ذلك سبق : أولاً تطبيق أهداف الاتفاقية المشار إليها حتى قبل الانضمام إليها بسنوات عديدة ثانياً : سد الثغرات أمام العابثين بالوسائل العلمية ومنعهم من استعمالها في القيام بنشاطات غير مسموح بها وبالتالي منع وقوع الفعل الجرم قبل وقوعه وذلك بمنع الامتلاك ومنع الاستيراد بالنسبة لغير المتوفر محلياً . ثالثاً : النص على ضوابط الاستعمال بالنسبة للمباح استخدامه أي امتلاك الوسائل للاستعمال العلمي والطبي والتقني . ففي إطار منع وحظر المواد الخطرة تشير المادة (25) من اللائحة التنفيذية للقانون رقم (7) لسنة 1982 ف الصادر بشأن حماية البيئة إلى أنه : " يحظر إلقاء المواد والنفايات المشعة في البيئة أو دفنها بغير الطريقة التي تعتمد عليها الهيئة بالتنسيق مع مركز البحوث النووية والجهات ذات العلاقة " .

كما ورد بالمادة (50) من الفصل الثالث من اللائحة وتحت عنوان (حماية البحار والثروة البحرية) " يحظر إلقاء المواد الصلبة أو السائلة على الشواطئ أو المياه الإقليمية للجماهيرية إلا بإذن من الهيئة وطبقاً للشروط والضوابط التي تضعها بقرار منها والمواد هي:

- 1) النفايات أو الفضلات أو المواد الملوثة أو السامة التي يحظر إلقاؤها
 - 2) المخلفات أو النفايات أو الفضلات والمواد التي يتطلب إلقاؤها تصريحاً خاصاً
- كما إشارات المادة (52) من اللائحة إلى : " يحظر إلقاء المواد المشعة والخطرة والغازات السامة ، وكذلك المفرقات بقصد تخزينها أو التخلص منها في الشواطئ أو المياه الإقليمية للجماهيرية العظمى " .
- أما في إطار الاستخدام السلمي المقنن للمواد والوسائل والتقنيات البيولوجية وغيرها من المواد ذات الطبيعة الخاصة فقد أشارت القوانين والنظم الإدارية إلى مسألة ضرورة الحصول على إذن من الجهة المختصة فمثلاً للحصول على أحد الوسائل التقنية في المجال الطبي فلا بد من الحصول على إذن باستخدام تلك الوسيلة من الجهة المختصة في قطاع الصحة وبالشروط الواردة في أحكام القانون الصحي رقم (106 لسنة 1973 ف) والقوانين المكملة لهذا القانون وليس ذلك فقط بل أن المشرع الليبي وضع شروط أخرى لاستيراد تلك الوسائل من الخارج ووضع أيضاً متطلبات لسير العمل بتلك الوسائل بالشكل الذي يجعل منها وسيلة خير وليست وسيلة خراب ودمار .

ثانياً : الأجهزة الفنية والإدارية المختصة بتطبيق أحكام التشريعات الليبية الخاصة بمنع الاستعمال الغير المشروع للمواد والوسائل والتقنيات البيولوجية والمواد الخطرة في الجماهيرية :

* كل التجارب القانونية تؤكد أن تنفيذ أي نوع من التشريعات لا يتم ألا من خلال هيئة أو جهاز أو منتظم يتولى العمل على وضع نصوص تلك التشريعات موضع التنفيذ ويتولى التنسيق مع كافة الجهات الداخلية والدولية للتعاون من أجل تطبيق أحكام الحماية القانونية المطلوب تحقيقها في أي مجال من المجالات . بالإضافة لهذا الدور الرسمي يقوم هذا المنتظم أو الجهاز بمهام أخرى تتمثل في احتضان المبادرات الفردية والجهود المشتركة للجمعيات الأهلية وبذل قصارى الجهد في سبيل مد يد العون المادي والمعنوي لتلك المؤسسات غير الحكومية . وعند التمعن في التشريعات التي أقرها النظام القانوني الليبي لتنظيم مسائل المتعلقة بالمتابعة والمراقبة والأشراف على الاستخدامات السلمية للمواد البيولوجية والمواد السامة والخطرة وبالتحديد في الأغراض الزراعية والطبية أن التشريع الليبي أوجد العديد من المؤسسات تتولى مهام الأشراف والمراقبة والتحقق من سلامة استعمال تلك المواد والوسائل والتقنيات للأغراض الزراعية والطبية .

(1) الهيئة العامة للبيئة :

هي أحد المؤسسات الوطنية التي تهم بشئون البيئة والحفاظ على الموارد الطبيعية وقد أنشئت هذه الجهة كتطوير للمركز ألفني لحماية البيئة (سابقا) . وقد أنشئت هذه الهيئة بموجب قرار اللجنة الشعبية العامة رقم (263) لسنة 1429م الموافق (1999ف) وقد حولت الهيئة القيام بالعديد من الواجبات والصلاحيات تتولى بموجبها منع كافة الاستخدامات التي من الممكن أن تسبب خرق للبيئة ونواميسها وهذا التوسع في الصلاحيات يستغرق أن لم نقل يشمل مراقبة ومنع استيراد أو تصنيع وتداول وبيع وشراء واستعمال المواد والمبيدات الكيماوية والوسائل والتقنيات البيولوجية والمواد السامة والخطرة ومنع تصنيعها على أرض الجماهيرية أو انتقالها من أي دولة أخرى ومراقبة وتنظيم الاستخدام المحدود والمسموح به للأغراض السلمية في المجالات الزراعية أو الطبية . والمشرع الليبي عندما أوجد هذه الجهة الرقابية لم يترك المجال لها وحدها بل أقر وجود العديد من المؤسسات والمراكز الرقابية التخصصية والبحثية لتتولى إحكام الطوق أمام كل المخالفين وتتولى أيضا المساعدة في بناء دفاع اجتماعي يحقق رغبة المجتمع الليبي في المساهمة في خلو الرقعة الجغرافية التي يقطنها من كل أسباب عدم الاستقرار البيئي ومن أهم تلك الأسباب استخدام المواد الكيماوية والوسائل والتقنيات البيولوجية والمواد السامة والخطرة .

وهذا ما يتأكد من خلال الصلاحيات الممنوحة للهيئة بموجب قانونها الأساسي والقوانين واللوائح والقرارات المكملة والتي تضمنت إعطاء كم هائل من الواجبات والصلاحيات نذكر منها على سبيل المثال لا الحصر :

— القيام بتسجيل كافة أنواع المواد التي قد ينتج عنها تلوث للبيئة بما فيها المبيدات المستخدمة لأغراض الصحة العامة والزراعة والبيطرة والتي يصدر بتحديددها قرار من اللجنة الشعبية للهيئة العامة للبيئة . (م/7/3)

— إصدار الآذونات اللازمة لتصنيع أو استيراد أو الإفراج أو بيع أو تداول المواد الكيماوية وغيرها من المواد التي قد ينتج عنها تلوث والتي يصدر بتحديداتها قرار من اللجنة الشعبية للهيئة ، ووضع الاشتراطات الفنية المتعلقة بالتصنيع بالداخل أو الاستيراد من الخارج أو التداول لدى المشتغلين في هذا المجال وكذلك إرشاد المستهلكين للمنتجات التي يدخل في تصنيعها مواد كيميائية . (م3/8)

— منع التخلص من النفايات والمواد السامة " يحظر إلقاء النفايات أو الفضلات أو المواد السامة في الشواطئ والمياه الإقليمية للجماهيرية ، وخول النص جهات الاختصاص العمل على تحديد ما يلي :

- (1) النفايات أو الفضلات والمواد السامة التي يحظر إلّاؤها .
 - (2) المخلفات والنفايات التي يتطلب إلّاؤها تصريحاً خاصاً
 - (3) وضع الشروط الخاصة بالتصريح بإلقاء المخلفات والنفايات . (م34)
- القيام بواجب تحريم إلقاء المواد الخطرة والغازات السامة في الأراضي الليبية والمياه الإقليمية التابعة للجماهيرية (م36)

- القيام بأعمال الرصد البيئي والرقابة البيئية وهذا ما ورد بالفقرة الرابعة من المادة (7) من اللائحة التنفيذية لقانون البيئة رقم (7) لسنة 1982 ف على أنه تتولى الهيئة العامة للبيئة القيام بكل ما من شأنه إعداد برامج الرصد البيئي والرقابة البيئية واعتمادها والالتزام بتنفيذها .

الهيئة العامة للبيئة هي نقطة الاتصال مع المنظمات والمؤسسات الدولية ذات العلاقة :

تعتبر مسألة تحديد نقطة اتصال وطنية من أهم متطلبات التدابير الوطنية التي تلتزم كل الدول الأطراف في أي اتفاقية من الاتفاقيات التي تنضم إليها بوضعها ضمن تشريعها الوطني وهذا ما اقتدى به النظام القانوني الليبي بحيث اعتبرت الهيئة العامة للبيئة هي نقطة الاتصال مع المنظمات والمؤسسات الدولية في شأن كل المسائل المتعلقة بالبيئة وهذا الحكم ورد ضمن متن المادة (18) من اللائحة التنفيذية للقانون رقم (7) لسنة 1982 ف الذي جاء فيه بأنه : " يكون المركز (الهيئة حالياً) هو الجهة الوطنية المختصة بشئون العلاقات البيئية بين الجماهيرية العظمى والدول والمنظمات والهيئات الدولية والإقليمية ويقوم بمشاركة الجهات الأخرى ذات العلاقة بدراسة ما يصدر عن تلك الدول والمنظمات من أعمال ، وإبداء المشورة الفنية وإعداد ما يلزم من مقترحات .

كما يختص الهيئة بالتوصية باتخاذ الإجراءات القانونية اللازمة لانضمام الجماهيرية للاتفاقيات الدولية والإقليمية المتعلقة بالبيئة والمشاركة في إعداد مشروعات القوانين واللوائح اللازمة لتنفيذ هذه الاتفاقيات .

(2) المركز الوطني للمواصفات والمعايير القياسية :

تم إنشاء هذا المركز بموجب قرار اللجنة الشعبية العامة رقم (62) لسنة 1985 ف للقيام بإعداد المواصفات والمعايير القياسية الليبية والعمل على إلزام كافة الجهات الوطنية وغيرها من الجهات التي تتعامل معها بتلك المواصفات والمعايير القياسية وعدم السماح باستيراد أو تصدير أو إنتاج أو تداول أي سلع أو مواد ألا بعد التأكد من مطابقتها للمواصفات والمعايير القياسية الليبية . وقد تم تعزيز موقف هذا المركز ودعمه بفضل صدور القانون رقم (5) لسنة 1991 الصادر بشأن المواصفات والمعايير القياسية والذي تم على أثره إعادة تنظيمه بموجب قرار اللجنة الشعبية العامة رقم (61) لسنة 1991 ف ومن أهم النتائج المترتبة على الدعم ألا محدود الذي قدمه المجتمع لهذا المركز أن تحول إلى فرق عمل وطنية متخصصة ومتنوعة بتنوع مجالات العلوم وتطبيقاتها تضم في عضويتها العاملين بالمركز وغيرهم من الكفاءات العاملة في مختلف القطاعات وعلى رأسها قطاع الجامعات والمعاهد العليا . وكان من أبرز الغايات التي يستهدفها المركز الوطني من خلال القيام المهام المنوطة به الحرص على سلامة المواطن وصحته وكذلك البيئة التي يعيش فيها دون أن يقتصر على مجال دون آخر فكان هذا المركز وسيلة من وسائل منع دخول المواد والوسائل والتقنيات البيولوجية ومنع استيراد غيرها من المواد السامة والمواد الخطرة . كيف لا يكون الأمر كذلك وتكوين اللجان الوطنية التي تعتبر عماد عمل المركز جل أعضائها من المهتمين بالمسائل الخاصة بحماية المستهلك والبيئة التي يعيش بين ربوعها .

وعند الحديث على خصائص العمل التقني الذي يقوم به المركز الوطني للمواصفات والمعايير القياسية نجد أنه عمل وقائي قبل أن يكون شيء آخر بحيث يتم تحديد المتطلبات التي يتطلبها العلماء من خلال المواصفة التي يتم وضعها لكل صناعة من الصناعات ولكل مادة من المواد ولكل سلعة من السلع ويتم متابعة توفر تلك المتطلبات بواسطة العديد من فلا يجوز منح شهادة إفراج لأي مادة من المواد موجودة بأحد المنافذ الحدودية بالنسبة للمواد المراد استيرادها إلا بعد التأكد من توفر المتطلبات التي هي في الحقيقة الشروط التي تتضمنها المواصفة الليبية المعتمدة وهذا الحال ينطبق على تلك المواد المزعم تصنيعها بالداخل ولا تقتصر رقابة المركز بل تمتد إلى الرقابة اللاحقة التي تصل دراسة الآثار السلبية على بعض التي سبق أن أعدت للمواصفة الليبية ونذكر مثلا مسألة السمية والمواد الخطرة في المواد الغذائية وبعض الأسباب المؤدية لانتشار الظواهر الصحية الأخرى . ويتم هذا العمل من خلال التعاون مع المراكز الرقابية ذات الطبيعة التخصصية ومن بينها مركز الرقابة والتفتيش على الأغذية .

(3) مركز الرقابة والتفتيش على الأغذية :

تم تأسيس هذا المركز بموجب قرار اللجنة الشعبية العامة للصحة والضمان الاجتماعي (سابقا) رقم (254) لسنة 1425م ليتولى المشاركة في أحكام الرقابة على سلامة استخدام المواد والسلع والخدمات التي تدخل في صناعة

الأغذية ومكملاتها وبالشكل التي يضمن تطبيق أحكام القانون الصحي رقم (106) لسنة 1973 في الذي سبق الإشارة إلى أحكامه المتعلقة باستخدام العوامل البيولوجية في الأغراض الطبية . بالإضافة إلى مراقبة المواد السامة والمواد الخطرة في الحصول على الأمصال وبعض العقاقير الطبية .

ولقد قام هذا المركز الحيوي بالعديد من الجهود من خلال التطبيق العملي للمهام المنوطة به في مجال حضر ومنع دخول الوسائل والمواد البيولوجية والمواد الخطرة والسامة إلى الجماهيرية وكانت وسيلته الرادعة الامتناع عن منح شهادات الإفراج لكل الوسائل والمواد المخطورة ومن خلال مراقبة استخدام الوسائل والعوامل المواد التي تم استخدامها للأغراض السلمية في القطاع الصحي وذلك بالتعاون مع القطاعات الوطنية ذات العلاقة

ثالثا : المراكز البحثية ودورها في دعم الأجهزة الرقابية

نحتاج المؤسسات و الجهات المختصة بالرقابة والتفتيش المختلفة لتجميع المعلومات والبيانات من مختلف المصادر اقليمية لدولية حول الأبحاث المتوصل إليها في المجالات الكيميائية والبيولوجية والتقنيات ذات الطبيعة الخطرة والمواد السامة . لك لكي تتمكن من النجاح في المهام المنوطة بها والتمثلة في منع الاستخدام غير الآمن للمواد الكيميائية والوسائل بيولوجية ومكافحة بعض حالات التجاوز من القطاع العام أو الأهلي وسبل معالجة بعض الآثار الجانبية للاستخدامات سلمية في المجالات الزراعة والطبية والهندسية سواء بالمؤسسات العلاجية أو التعليمية أو الصناعية أو في أماكن التداول ، المصنع أو عبر المنفذ الحدودي أو الميناء إلى البيت أو مكان العمل وكافة المعامل والمصانع والوحدات الإنتاجية . ومن ثمة المراكز البحثية التي تعتبر أدوات مساعدة للأجهزة الرقابية نذكر على سبيل المثال لا الحصر :

- مركز البحوث الزراعية .
- مركز بحوث الأحياء البحرية .
- مركز البحوث الدوائية والصيدلانية .
- مركز التقنيات الحيوية .

أساليب التي تنتهجها المؤسسات البحثية لتوفير قاعدة بيانات لصالح الأجهزة الرقابية :

توفير قاعدة بيانات من خلال التعاون مع المؤسسات والمراكز العلمية العالمية والمنظمات الدولية المتخصصة في شطاطات المشاهدة ومن خلال تشجيع الدراسات المتخصصة بقصد الحد من الآثار السلبية للاستخدامات السلمية .

- إعداد سجلات خاصة بالمعلومات التي يتم توفيرها من مختلف المصادر على أن يتضمن تبويب البيانات في إطار نوعي كلاً على حده بحيث يتم وضع قوائم دقيقة لأنواع المواد الكيميائية أو العوامل البيولوجية أو المواد الخطرة والسموم فنجد مثلاً فيما يعلق بمسألة السموم من الممكن دخول بعض المواد التي تحتوي على نسبة من

السموم في حالة عدم متابعة الأبحاث الخاصة بها بواسطة المراكز البحثية المنوه عنها التي توفر آخر المستجدات في مسألة درجة السمية وطرق اكتشافها والأجهزة المتطورة لقياسها وهذا الدور كفله القانون الليبي لمركز الوطني للمواصفات والمعايير القياسية بالإضافة لمركز الرقابة والتفتيش على الأغذية ومن هنا تأتي أهمية الدور العلمي للمراكز المتخصصة في تحقيق إحكام الرقابة ودقتها بحيث يتم منع استيرادها وبالتالي إعطاء فرصة للسلطات الرقابية في المنافذ الحدودية والمواني والمطارات للقيام بالواجبات المنوطة بها وفقاً للقوانين الخاصة بمنع الاستعمال غير المشروع للمواد الخطرة والسامة وتأمين الاستخدام السلمي الآمن عند الحاجة وبالضوابط التي تضعها القوانين واللوائح والقرارات والنظم الإدارية التي يكفلها النظام القانون الليبي في هذا المجال . - بتوفر المعلومات تقوم القطاعات الفنية والإدارية ذات العلاقة بوضع نظام محكم يتضمن إعداد قوائم بالمواد والسلع التي تمثل خطورة ومن بينها المواد والعوامل والتقنيات البيولوجية والمواد الخطرة والسامة المخطورة دولياً والتي ثبت حظرها بناء على الدراسات التي قدمت من المراكز العلمية وبالتالي تمكين الأجهزة الضبطية من منع دخول تلك المواد إلى داخل الجماهيرية العظمى . وقوائم أخرى بالمواد التي ممن الممكن استخدامها ولكن بشيء من الحذر فيمنح تصريح مشروط بدخولها كضمان لتحقيق الأهداف التي يسعى إليها المجتمع الليبي من خلال إقرار القوانين والقرارات واللوائح الصادرة بشأن منع انتقال المواد والوسائل الخطرة إلى الجماهيرية وبالتالي منع استخدامها بشتى الطرق .

- وجلى مما سبق سرده من أحكام ومن إجراءات وتطبيقات عملية يتأكد الممعن في النظر بأن المشرع وضع خطة متكاملة شروط تستهدف تحقيق الحماية الكافية للمواد والوسائل البيولوجية والتكسينية (السمية) سواء من خلال الإجراءات المسبقة قبل الامتلاك أو قبل إدخالها للجماهيرية للاستخدام السلمي في المجال الطبي والزراعي والهندسي . ولم يقتصر النظام القانوني على سن التشريعات فقط ليكون عملاً دعائياً بل حث جميع فئات المجتمع على التعاون على تنفيذ تلك التشريعات لأهميتها وصدق دليل على هذا القول ما تضمنته كافة القوانين واللوائح والقرارات الليبية الصادرة في الشأن ذاته من تأكيد على مسألة وجوب تطبيق كل تلك التشريعات على كل المقيمين على أرض الجماهيرية من مواطنين وغير مواطنين زد على كونه أن مسألة تطبيق التشريعات في النظام القانوني الليبي هي حق لكل الليبيين فهو حق لهم عندما يضعونه كقاعدة قانونية عبر مؤتمرات الشعب التي تختص بوضع كافة التشريعات وهو حق لهم عندما يلجئون للسلطات القضائية للمطالبة بتطبيق أي نص وضد كل من كان أو بواسطة انضمامهم للجمعيات الأهلية التي يشكلونها لممارسة اهتماماتهم المختلفة ومن تلك الاهتمامات الخاصة بحماية الإنسان والبيئة التي يعيش فيها ..

(informal transcript of the English interpretation)

My paper may be quite long, however, I will try to summarise certain legislations, which are implemented in my country. I will talk about the legislation as well as the research centres, which provide scientific support to the supervisory bodies. We have classified regulations and the laws in accordance with the Convention of 1981 as before our acceding to the Convention and the laws and regulations, which were enacted after we acceded to the Convention.

When we reviewed the legislation regarding the specialised research in the field of the use of toxic material and biological material in agriculture and industry, we looked at the laws, which are implemented on the use of these biological materials, especially for the peaceful uses. And in every stage of the use, such as the importation and the medical equipment, the manufacturing and the handling, the legal system has enacted a number of rules and regulations as well as administrative procedures to prohibit the use of unauthorised agents and to punish the violators.

There is also legislation regarding the approved use of certain agents for peaceful uses and other laws and regulations. There were laws and regulations, which were enacted before we acceded to the Convention, which organised the peaceful uses of biological and chemical as well as toxic agents and materials, which may be used in the field of medicine. These laws unfortunately were too general and did not deal with specific biological or chemical agents, and I believe that this applies also to the Geneva Protocol.

There are rules and regulations regarding the agricultural sector, Law No. 27 of 1986 regarding the protection of plants. Libya has had a great experience in the enactment of a legislation regarding the use of chemical products as well as biological products and hazardous and toxic agents. We refer here to Chapter 3 of this law.

Rules and regulations regarding the health sector, such as Law No. 106 of 1973. This law took up a great deal of issues, which are related to the legal protection, again for the peaceful uses of biological processes in the medical field. For instance, this law organises the laboratory tests in the field of bacteriology and pathology.

Article 128 of the law stipulates that no person can carry out laboratory tests or research unless he is a medical doctor and unless he is fully qualified to carry out such research and laboratory tests. This law in fact refers also to a number of conditions, which have to be fulfilled before any such operations can be carried out and to prevent any wrongdoing in this field.

Paragraph 2 of the same article also refers to the laboratory tests and research, which is mentioned in the first paragraph. When we talk about laboratory tests we mean first of all research analysis and laboratory tests in the bio-medical chemistry field. 2. Research analysis and laboratory tests concerning bacteria and research analysis as well as laboratory tests in the field of pathology. For the preparation of vaccine sera and bio-products, from the text of the law the Libyan legal system tried to cover the special professions and to ensure their protection from being infiltrated by unqualified people and wrongdoers.

Health law, in Articles 125, 124, 123 and 122 also covers the functions, which complement the medical profession, such as the carrying out of medical tests. Controls have been laid down to make sure that no wrongdoing takes place in the medical laboratories.

As to Section 1.3.2 of the above-mentioned law, this section covers the movement of toxic and hazardous materials and any person who tries to transfer medical products without a permit or prior authorisation is punishable by law.

The regulations and the laws, which were enacted after acceding to the Convention: law on the protection of the environment No. 7 of 1982 and the Executive Order. In 1982, Law No. 7 was enacted regarding the environment protection. Articles 50, 51, 52 and 57 provide for a number of controls regarding the various uses of biotechnologies, toxic and hazardous material in the following manner. Controlling the import, use, manufacture and transfer of all pesticides and chemical products in order to protect water sources from pollution. The legislator was also interested in setting up a control authority, which would carry out control and inspection of the manufacturing, import, use and transfer of these products, especially those technologies which are not available in Libya and which have to be imported. 2. The need to determine the toxicity of pesticide residues and 3. controlling the transfer, exchange of toxic, chemical, pesticide as well as solid waste and liquid waste.

Law No. 15 of 2003 regarding environmental protection. This law supplements Law No. 7, the most important provision of which regards the handling of biotechnologies and toxins and hazardous materials for peaceful uses. Therefore it is closely linked with our Convention.

There are certain conditions, which have to be fulfilled, such as the permits. There is a need to carry out a risk assessment of the uses of genetically modified organisms and to assess their effect on national species. Hazardous material may not be transferred, especially those hazardous materials which may release dust, small particles or vapours and which may lead to the pollution of the environment.

These materials have to be tightly packaged in accordance with Article 15. Highly volatile organic material such as solvents and acids must also be tightly packaged. Any toxic or poisonous material, which may pollute the marine environment, is prohibited. Toxic bait may not be used for fishing and there is also a need to determine the toxicity of chemical pesticide residues and their effect on agriculture.

As to the administrative bodies, which are in charge of the implementation and enforcement of this legislation, the implementation of legal provisions can only be guaranteed through an authority, which is responsible for enforcement in coordination with all the other authorities and bodies. This is extremely important in order to provide full protection.

The general authority for the environment. This is one of the institutions, which is concerned with the protection of natural resources. This authority is responsible for a number of functions and it controls the uses of certain biotechnologies and toxic material, which may lead to the pollution of the environment. They control of the manufacture, use, transfer and movements of all such materials.

The National Centre for the Specifications and Standards. This centre was set up by virtue of decision 62 of 1985, which sets up the specifications and standards that have to be fulfilled by all the national bodies that handle such biological technologies and toxic and hazardous material.

The Centre for Inspection of Food Products. This centre was set up by virtue of decision 254 of 1989 regarding the use of products and the manufacture of food. And here I would like to refer

also to Health law No. 106 of 1973, which refers to bacteriological agents for medical purposes and the control of sera as well as medical drugs.

Research centres and their role in providing support to surveillance centres. These institutions in fact collate and collect data and information on chemical and biological research as well as research on technologies related to toxic substances. Some of these centres, as an example we have the Centre for Agricultural Research, the Centre for Marine Organism Research and the Centre for Pharmaceutical Research and the Centre for Biotechnologies. All these centres cooperate together and cooperate with relevant international institutions in order to prevent the adverse effects of such substances. They also set up special registers. Lists are drawn up of the biological and toxic substances.

The Netherlands

I would like to give a brief introduction to Working Paper number 14 by the Netherlands, with the title "Preventing unauthorized acquisition of pathogenic agents and toxins: a legal Patchwork".

At this moment in time, the Netherlands is in a phase of reviewing its national legislation implementing the prohibitions set out in the BTWC. To this end an interagency working group was set up with the aim to identify the issues we have to address. The experts identified to be part of this 'Contact group on the implementation of the biological weapons convention' are also responsible in preparing the meeting of experts we have now more in detail and, if possible, attend the meetings. In this way, ideas shared at this meeting of experts can be directly incorporated in our endeavour to strengthen our national implementing legislation and the enforcement thereof.

In our working paper the emphasis has been put on one of the issues we feel that has to be addressed in the coming years: the prevention of unauthorized acquisition of agents and toxins from our own laboratories. Both from the point of view of bio terrorism, as well as the prevention of proliferation, we think that this is an important issue, that has not received due consideration and attention since the Netherlands adopted legislation to implement the Convention back in 1981.

The paper generally describes some areas of concern related to working with/handling biological agents and toxins if looked at from the perspective of unauthorized acquisition, to which I will now refer to as bio-security. Amongst them are the areas of (physical) access to laboratories and premises, as well as integrity of personnel. The paper then suggests some measures that could be taken to tackle some of these areas of concern.

The question is which areas of concern have already been addressed in national legislation or regulations and whether they include some of the measures mentioned in the paper. If so, the question would arise whether this legislation or these regulations are fully enforced and/or monitored.

The paper continues by providing a quick glance at some applicable legislation, regulations, and oversight bodies or agencies currently in place within the Netherlands. More applicable legislation can be found on the CD-ROM, provided by the Secretariat, and the legal

questionnaire that has been presented as part of the paper by the Presidency of the European Union.

At this point I would like to stress that the Netherlands is still in the 'review phase'. We are not yet sure we have identified all legislation, relevant to either the implementation of the prohibitions of the convention, or the specific topics of bio-safety and bio-security. Of course, the secretariat and States Parties will be informed of new identified measures.

Nevertheless, this preliminary overview of legislation and monitoring agencies and inspectorates is already sufficient to be able to conclude that not all the identified areas of concern have been covered, nor that all suggested measures have been taken. Furthermore, we also concluded, like other delegations have done in their presentations, that the focus of existing legislation is not on bio-security aspects but is often aimed at for instance health and safety, or protecting the environment. The same goes for the focus of monitoring, inspection or enforcement.

We could say that both legislation and monitoring are not optimal at this moment yet. Besides that, the situation is not static: for instance, the administrative burden related to the various licensing schemes is sometimes felt to be too costly. There is a general tendency towards more self regulation, requiring only notification of some intended activities, not a license. Another trend is that the monitoring and enforcement of legislation and regulations are being focused on priority areas. These general trends have also to be taken into account when addressing the issue of bio-security.

The paper itself concludes with identifying some questions that the Netherlands has to address in tackling the problem of bio-security. Other states might also share these questions. Later this week we hope to come back to some of them and share with delegations what we have learned during the discussions.

Iran

Following my morning intervention, please permit me to add some information on biosafety. Maintaining a healthy and secure environment is an integrated part of policy of the Ministry of Health and Medical Education. The Ministry has approved extraordinary budget for promotion of biosafety, GLP and GMP. National health security is challenged by naturally occurring endemic, emerging and re-emerging disease threats. Health security can also be threatened by the accidental or intentional release of pathogenic microorganisms and toxins.

The overall goal of the national biosafety program is to reduce, to the extent possible, the spread of disease caused by accidents, inappropriate handling or usage of pathogenic microorganisms.

The biosafety objectives are as follows:

- To promote safe practices in the handling of pathogenic microorganisms based on the best practices standards stipulated in the international rules and regulations in:
 1. Health care facilities
 2. Vaccine production facilities
 3. Laboratories

4. Transport of samples

- To strengthen, coordinate and evaluate efforts for the establishment of a national plan of action for the safe handling of infectious substances.
- To promote safety standards in the construction of laboratories and facilities.

The national biosafety program of Iran applies the WHO's guidelines such as:

1. Laboratory biosafety manual, second edition, WHO/CDS/CSR/LYO/2003.4
2. Safe health care waste management, included in www.Healthcarewaste.org
3. Guidelines on prevention and control of hospital associated infections, SEA-HLM-343, Jan 2002
4. Guidelines for the safe transport of infectious substances and diagnostic specimens, included in www.who.int/emc/biosafety.html

Japan

Possible Measures for Strengthening Biosecurity

Method of Approach

- Review of measures adopted to regulate dangerous pathogens
- Compilation of possible measures considered to be objectively effective for strengthening biosecurity

The Review was undertaken in the following areas:

1. Lists of controlled pathogens
2. Monitoring of facilities and individuals that handle controlled pathogens
3. Monitoring the transfer of controlled pathogens
4. Physical security measures applied to laboratories and other facilities handling controlled pathogens

1. Lists of controlled pathogens

Core List:

- Pathogens found commonly on all controlled pathogen lists, including the lists of pathogens that are controlled either for biosecurity purposes or for export control purposes
- This List represents the most dangerous pathogens in terms of their utility in the development and manufacturing of BW.

Core List (1)

| | | |
|-------|-------------|---|
| Human | Viruses | Crimean-Congo hemorrhagic fever Eastern equine encephalitis Ebola Marburg Monkey pox Rift valley fever Tick-borne Encephalitis Complex viruses Variola Venezualan equine encephalitis |
| | Rickettsiae | Rickettsia prowazekii Rickettsia rickettsii |
| | Bacteria | Bacillus anthracis Brucella abortus Franciscella tularensis Yersinia pestis |

Core List (2)

| | | |
|--------|---------|--|
| Human | Toxins | Botulinum toxin Clostridium perfringens Ricin Saxitoxin Shiga toxin Tetrodotoxin |
| | | |
| Animal | Viruses | African swine fever Avian influenza Bluetongue Foot and mouth disease Goat pox virus Japanese encephalitis Newcastle disease Peste des petits ruminants virus Rinderpest Sheep pox Swine fever virus Vesicular stomatitis |
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Possible measure (A)

Establish a national list of dangerous pathogens of which possession, use, and transfer should be controlled

The Core List can serve as a basis.

Each country could add other pathogens to the list according to domestic requirements.

- The following factors can be considered:
- Effect on human health of exposure to the agent;
- To what extent the agent is contagious;
- Methods of transmission to humans;
- Availability and effectiveness of immunizations and treatments for any resulting illnesses.

2. Monitoring of facilities and individuals that handle controlled pathogens

Possible measure (B)

Establishment of a national authority at the national level to be responsible for implementation of national biosecurity measures

- National authorities should serve as the central agency within the national government for tracking and collating registrations and permits related to the possession, use, and transfer of controlled pathogens.
- This function can be assigned to existing organizations within the national government.
- The task may be split among several organizations.

Possible measures (C)

Introduction of registration systems for facilities and individuals seeking to possess, use and transfer controlled pathogens

The following information should be recorded by national authorities:

- Name and address of the facility and individuals;
- Reason for requesting registration;
- Name and address of the physical facility where the pathogens will be stored;
- Name and contact information for the biosecurity official at the facility;
- Detailed information on the physical and procedural safety and security measures taken at the facility;
- Names and contact information for staff members who will access the pathogens.

Possible measures (D)

Introduction of inspection system

- National authorities and/or law enforcement agencies may be empowered to have access to the facilities, verify the registered information and security measures in the facilities, and then make appropriate recommendations where necessary.

3. Monitoring of the transfer of controlled pathogens

Possible measures (E)

Introduction of a national registration system for transfer of a controlled pathogen

- Only registered facilities and individuals can transfer (ship and receive) controlled pathogens
- National authorities should be provided with, and collate, separate notices of the intent to transfer pathogens by both sides before shipment.

Possible measure (F)

Establishment of packing and labeling requirements of pathogens for preventing illicit access during shipment

- Water-tight primary receptacle and secondary packaging;
- Highly durable outer packaging;
- Appropriate package labeling, including biohazard labeling and other hazard markings;
- Tamperproof seals.

4. Physical security measures applied to laboratories and other facilities handling controlled pathogens

Possible measures (G)

Establishment of clear guidelines and requirements in the area of physical security measures and operational and procedural guidelines in order to prevent unauthorized access to controlled pathogens.

- Nomination of persons-in-charge of the facility's security (could be a single person responsible for both biosafety and biosecurity).
- Establishment of access controlled areas:
 - Locked doors and card keys;
 - Suitable secure containers for storing controlled pathogens;
 - Procedures to record entries and exits;
 - Background checks of persons who handle controlled pathogens;
 - Identification badges.
- Logs of all items brought into or out of restricted access areas:
 - Screening of items brought out of the facility;
 - Log of all items brought into the facility;
 - Inventory of pathogens in the facility.

Tuesday 26 August 2003

Czech Republic

The Czech Armed Forces and BWTC

1. A short history of biological research in the Armed Forces after WW II

Military biological activities in the Czechoslovak Army after WW I and WW II were performed within the framework of military medical service without special organization, funding, research etc.

One example of the use of biological weapon (botulinal toxin) in our country was described during WW II – the assassination of R. Heydrich, Nazi “Protector“ of Bohemia and Moravia by means of a grenade impregnated with this toxin. Although Heydrich’s wounds were comparatively minor, he died unexpectedly several days after the attack.

The year 1951 was a milestone for biological research in the Czechoslovak Army. Till this year, no biological research was conducted in the Army.

After the foundation (1951) of the Purkyně Military Medical Academy in Hradec Králové (PMMA) and the Department of Microbiology of the Academy and its detached workplace in Prague (Na Ořeškovce) – the Microbiological Section, biological activities started. These activities were exclusively aimed at peaceful purposes – no biological offensive research was performed.

In 1961, the Military Institute of Hygiene, Epidemiology and Microbiology (VÚHEM) conducted research in the field of diagnostic techniques, expertise, support of the Army in peace time etc. At that time, the “Na Ořeškovce“ workplace de facto and de jure did not exist and all research activities were concentrated on PMMA and VÚHEM (Laboratory No. 201 Nový Hrádek) (later on also in Těchonín). In general, the problems solved can be summarized in the following areas:

- Pathogenetic studies on airborne infections (influenza virus, VEE, Francisella tularensis models)
- Immunologic and diagnostic techniques (toxoplasmosis) including cell-mediated immunity and the effects of biological response modifiers
- Nosocomial infections, intestinal infections, inhalation infections (especially influenza)
- Human parasitology
- Preparation of purified virus antigens etc.

During the 1990s, Institute of Immunology solved the problems of induction, regulation and expression of immune response to intracellular bacterial pathogens (Francisella tularensis model), immunomodulation and immunotoxic effects of xenobiotics incl. vaccines and clinical application of two dimensional gel electrophoresis with computer evaluation for diagnostics of tumor diseases.

Sometimes it is difficult to differentiate between offensive and defensive research – e.g. identification of biological agents, their isolation and characterization, the study of properties, cultivation, in vitro and in vivo experiments and production in small quantities – it is defensive

research, however, an a necessary step for further military evaluation. The next steps that are on the border line between defensive and offensive research – modifications of the agents to decrease or increase their virulence, stabilization, production of sufficient quantities for preclinical (defensive) testing or for methods of dispersion (for peaceful purposes to know the pathogenesis of infections, spreading, and anthroppo-zoonotic transition) (for military purposes to know the best methods of dispersion) - are possible and the differentiation is easier but not absolute. Production of large quantities, weaponization and field testing are examples of clear offensive research. Modelling on computers can perform all these activities and differentiation is also difficult. The final result – the biological weapon or vaccine is clearly distinguished for military and peaceful purposes though some doubts exist – e.g. vaccination against some diseases not occurring in the region can suggest that military troops are protected against diseases possibly caused by biological weapons (BW) or if are assigned on a mission in quite another region. During this process, biotechnology is of high importance because of possible modifications of normal infection agents modified to be resistant to treatment, more virulence etc. i.e. an effective way to obtain BW.

2. The Czech Armed Forces and BWTC

Following the signature of the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (biological) and Toxin Weapons and on their Destruction (BWTC) the situation was completely changed. Research activities were focused on the problems of hygienic and epidemiological care in the Army. All biological research activities have had an exclusively defensive character; they have never been concerned with offensive biological research such as weapons, increasing of virulence, modification of the properties of biological agents make them more dangerous to health (new pathogens) etc.

All activities of the Czech Army in this field were declared by the Czech Republic (1992) at the Confidence Building Measures (CBM).

3. Preparation and cooperation of the Czech Army for implementation of the BWTC

The responsibility of the Czech Army Medical Service is fully understandable. There are existing bodies in the Ministry of Defense responsible for these topics, e.g. collection of data within the Army relevant for BWTC. The work is based on a group of experts (most of them you can see at the end of this contribution). The first mapping of all these activities was conducted and declared within the Czech declaration of CBM.

At present, the Czech Army is exhaustively informed about all activities performed within it, and practically speaking, it is prepared for declaration, verification and other obligations according to the future and agreed Verification Protocol.

The Czech Army has cooperated/cooperates with State Institutions responding to this field, i.e. SÚJB (The State Office for Nuclear Safety). The Army's representatives are involved in relevant Commission and they are/were members of the Czech Delegation to the Ad Hoc Group and other important bodies. Documents BWC/AD HOC GROUP/WP.103 (17 September 1996): "List of terms and definitions" and BWC/AD HOC GROUP/WP.323 (7 October 1998): "Definitions – proposed replacements" were elaborated in close cooperation between the Army and the Ministry of Health (Assoc. Prof. B. Kříž, MD, PhD). Some papers in the literature were published in cooperation with the workers of the SÚJB and other interested institutions (e.g.

“Biological agents of high risk. Introduction into the management of biological events“, in Czech). (A. Macela, Ed.) SÚJB Prague, 2002, 137 p.; Středa, L., Bajgar, J.: “Endeavours to control the ban on biological weapons continue“ (in Czech). International Relations, 36, 4/2001, 56-80; Patočka, J., Středa, L.: “Toxins from the view of international verification regimes“ (in Czech). Forensic Medicine 47, 2002, 18-28 or Patočka, J., Středa, L.: “Plant toxic proteins and their current significance for warfare and medicine.“ J. Appl. Biomed. 2003, in press)

All these activities are not only focused on information dealing with BWTC and the possible elaboration of the Verification Protocol but they are connected also with protection against the threat of bio-terrorism. This approach can be documented by different lectures for medical personnel on different levels held mostly at the PMMA. The top lectures can be mentioned, namely

“Extraordinary Situations and the Rescue Integrated System in Light of the Integration of the Czech Republic into the EU“ held at the Czech Parliament, Prague (26 November 2001), (J. Patočka, M. Šplíňo and S. Býma of the Czech Army were invited speakers) and a press conference organized by the Czech Academy of Sciences (20 February 2003, Prague) with the active participation of Army representatives (J. Bajgar, J. Fusek, J. Patočka). A book published last year is also connected with these topics: “Biological and Chemical Terrorism. Information for Everybody“ (in Czech) (R. Prymula, Ed.). Grada Publishing, Limited, Avicenum, Prague 2002, 150 p.

4. Rumours about the Center for Biological Protection in Těchonín and the data bank at the Central Military Hospital Prague

Mention of the Czech BW occurred in an article by B. Garrett entitled “Czech Biological Weapons?“ (ASA Newsletter, 94-2, 1994, p. 7). The situation was as follows:

Construction of the Těchonín Institute started in 1968. Research activity began in 1972 under name of Military Institute of Hygiene, Epidemiology and Microbiology (VUHEM), Prague. The Těchonín facility was dedicated to the research of pathogenesis, prophylaxis and therapy of infectious diseases with a special focus on infections transferred by air. In September 1977, the heading was changed and the Institute was made part of the Military Medical Research and Postgraduate Training Institute (VLVDÚ), later the Purkyně Military Medical Academy (VLA, 1988), Hradec Králové. In 1994, it was drastically reduced to its remaining parts – the immunological laboratories and vivarium (12 workers) and it was made part of the Institute of Immunology (PMMA). From the year 2002, the Institute was again made part of the Central Military Health Institute in Prague. Up to now, no biological research has been conducted.

However, in light of the threat of bio-terrorism it was decided to construct a new facility in Těchonín, The Center of Biological Protection of the Czech Army, for isolation, hospitalization and treatment of patients with highly infectious diseases and including the necessary laboratory equipment. A high level of biological protection (BL 4) is planned. This proposal was seriously declared to the relevant international organization.

Another story is dealing with the data bank at the Central Military Hospital in Prague. In 1994, the existence of a bank of virus strains at the Central Military Hospital in Prague as well as at the Těchonín Institute was acknowledged. The existence of Těchonín was declared and its activity and structure has been described since 1992 in the declaration of the Czech Republic

within the CBM framework. Nevertheless, the Minister of Defence ordered the bank to be destroyed and this was done that same year. Unfortunately, this bank of pathogens (positive controls for antisera) unique and necessary for diagnostic purposes was destroyed without any possibility of renewing this bank for its original peaceful purposes.

5. Present biological research in the Army of the Czech Republic

Present biological research is conducted at two Departments of the PMMA only. It can be summarized as follows:

Department of Epidemiology

New adjuvanted hepatitis B vaccine in haemodialysis patients
Vaccination against Tick-borne encephalitis
New conjugated 11-valent pneumococcal vaccine
New conjugated meningococcal vaccine
New adjuvanted hepatitis B vaccine
Influenza vaccines – intradermally administered
Combined vaccine against hepatitis A and B – a two-dose schedule
Topical problems in disinfections and antisepsis in the Czech Army
The use of foams for disinfections in Czech Army conditions
Expertise activities for field conditions
Express diagnosis of hazardous infections with emphasis on hantaviruses
European study on nosocomial infections
It is quite clear that these activities are in full compliance with the BWTC.

Institute for Molecular Pathology (the former Institute of Radiobiology and Immunology) – biological part

Advanced technologies in the identification and detection of BW agents
The proteome center for the study of intracellular parasitism of bacteria
The effect of tick saliva on the transmission of *Borrelia burgdorferi*
Identification and typing of the *Coxiella burnetii* microbe

The first two topics are of great interest because the final results can contribute to better understanding and protection including diagnosis and treatment of health injuries caused by infectious agents and toxins including biological warfare agents.

For the education of both military and civilian specialists, it is planned to construct at the Military Medical Academy a “Teaching laboratory for advanced technologies in identification of B- and C-agents“. Some of its features are described in the next section.

After finishing the above-mentioned projects, the research activities of the Army will continue and in its final output, the results will make a substantial contribution to protection against biological and toxin weapons.

6. Some comments on facilities, equipment and personnel

Facilities

The specifications, purpose, description of specific activities, the owner etc. must be clearly indicated as it is in the case of Těchonín.

The exact location including plan is necessary condition for further verification.

Funding may differ, however, it must be clearly declared. The main financial source for our facility will be the Ministry of Defense but other sources such as from interested parties including international ones are not excluded.

Equipment

It is supposed that the necessary basic equipment is *conditio sine qua non*.

Other equipment will be very dependent on financial sources. It will be focused mostly on easy and quick diagnosis of infectious diseases, toxin intoxications, laboratory and hospital equipment permitting the saving of life functions on a high level. From these instruments, the detection equipment for applications in molecular biology and ELISA, real time PCR, biohazard boxes BL 3, protection equipment etc. is of interest.

Computer relevant programs are very important beginning of data bank of pathogens, treatment procedures etc. through actualized data for the treatment.

Protection (both individual and collective) is necessary to prevent the unauthorized outbreak of diseases and for the control of international authority.

Biohazard containment/decontamination equipment responding to the declared biosafety level must be on highly sophisticated basis.

Microencapsulation equipment, Downstream processing/drying equipment for microorganisms/toxins, Detection/Assay systems for microorganisms/toxins/genetic material, Fermenter/Bioreactor equipment (if any) will be clearly declared, accessible to verification and protected against misuse for prohibited purposes. These types of equipment can be considered very important for future verification

Personnel

-the professional staff (scientific workers, and environmental, occupational health, animal health, public health, and emergency management experts) will be chosen according to the purposes of the facility

-security of the work, personal security clearances and all necessary conditions for excluding the failure by the human factor must be minimized

-maintenance of the approved facility will be secured.

-administrative and information technology (bioinformatics, intra/extra-facility communications must prevent the unauthorized release of confidential information

-sanitation will be on the same level as maintenance

-equal distribution of highly educated personnel having the ability to exchange the information (e.g. to organize scientific meetings etc.), to learn, organize and lead a research team (knowledge of epidemiology and microbiology of high virulence agents, knowledge of laboratory diagnostic processing, biotechnology and technological equipment, publication activity, i.e. experts in the field of biological research). Young scientists, other experts, laboratory assistants, security personnel and others will be assessed according to necessity, tasks and the possibilities of real conditions.

United Kingdom

Presentation on Emergency Preparedness and Response

Introduction

1. This presentation summarises the UK's contingency plans, consequence management aspects, training and public dissemination of information. It also covers planned legislation.

Contingency plans

2. The Civil Contingencies Secretariat (CCS) was established in July 2001 at the Cabinet Office to improve the resilience of central Government and the UK. Resilience is defined as the ability to handle any disruptive challenges that can lead to, or result in, crisis - not just terrorism but eventualities such as floods or fuel crises. The CCS is a specific unit with responsibility for emergency planning and for assessing, anticipating and preventing future crises. It drives the progress of all Government departments involved in responding to emergencies. The CCS reports to the Prime Minister.

3. The aim of the CCS is to improve the UK's resilience to disruptive challenge through working with others inside and outside Government on anticipation, preparation, prevention and resolution. Its current objectives are to:

- Lead horizon scanning activity to identify and assess potential and imminent disruptive challenges to the domestic UK and assist in the development of an integrated response. Build partnerships with other organisations to develop and share best practice in horizon scanning and develop the knowledge of the UK's critical networks and infrastructure.
- Ensure that the Government can continue to function and deliver public services during crises, working with Departments and other Secretariats in the Cabinet Office to ensure that plans and systems to cover the full range of potential disruption are in place and exercised.
- Lead the delivery of improved resilience to disruption across government and the public sector, including supporting Ministers in developing policy, agreeing priorities and planning assumptions and ensuring that core response capabilities are developed accordingly. This includes the development and promulgation of doctrine.
- Improve the capability of all levels of government, the wider public sector and the private and voluntary sectors to prepare for, respond to and manage potential challenges, through development of key skills and awareness.

Consequence management

4. The CCS works very closely with the Home Office, which takes the central government lead in dealing with chemical, biological, radiological and nuclear (CBRN) threats. The Home Office also works with stakeholders to ensure that capabilities are in place to respond effectively to the consequences of CBRN incidents. The emergency services are the first responders in the UK.

Their capability to cope with threats is the key to minimising loss of life and since 9/11 have had additional investment in their equipment and training. This includes:

- Under a £5 million programme, the Department of Health has provided 360 mobile decontamination units and 7,250 national specification Personal Protection Equipment suits around the UK, which will enable the Ambulance Service and hospital Accident and Emergency Departments to treat people contaminated with CBRN material.
- The CBRN Police Training Centre has been established at the Defence Nuclear Biological and Chemical Centre at Winterbourne Gunner.
- As of March 2003 UK police forces have had over 2,350 officers trained and equipped in CBRN response, and this training roll-out is continuing.
- Arrangements are in place for the Fire Service to support the Ambulance Service by decontaminating people at a CBRN incident.
- £56 million has been made available to the Fire Service to provide a national mass decontamination capability. Procurement of equipment (response vehicles, portable contamination facilities and specialist protective clothing) is underway, supported by development of appropriate training.
- The Department of Health, in conjunction with Health Departments in Devolved Administrations, is funding measures to counter bioterrorism. This entails:
 - A UK Reserve National Stock of vaccines and antibiotics suitable for the treatment of infectious diseases and specialist equipment has been built up. Guidance on handling infectious diseases was disseminated throughout the National Health Service in October 2001.
 - Twelve regional Smallpox Response groups are being established around the UK. Smallpox Vaccine will be offered to volunteer healthcare personnel who will be able to react quickly and work safely with patients of actual or suspected smallpox. Specialist military personnel will also receive vaccination against smallpox. The UK has also identified reference laboratory centres capable of rapid diagnosis of the disease.
 - £16 m was allocated by the Department of Health in 2001/02 to provide medical countermeasures against CBRN agents and a further £80 million has been allocated for 2002/03, including spending on extra vaccines and antibiotics.

The Department of Health

5. The Department of Health's Emergency Planning Coordination Unit is responsible for the coordination of contingency planning to maintain the state of readiness of the National Health Service (NHS) to respond to major incidents. It liaises with other Government departments on matters related to emergency planning and acts as the UK's representation on key European and international committees for consequence management and policy development. The Department of Health issued guidance on 'Planning for Major Incidents' in November 1998 and for responding to the 'Deliberate Release of Biological and Chemical Agents' in March 2000. In September 2001, following the terrorist attack in the US, the NHS was asked to review its emergency plans. As part of this review, the Department of Health expanded its guidance to include a series of 'aide-memoire' to assist Regional Directors of Public Health, Directors of Public Health, Consultants in Communicable Disease Control and clinicians at local level in planning their public health response. DH guidance is complemented by operational guidance published by the Public Health Laboratory Service (PHLS). The dynamic process of emergency

planning led to a review and updating of the DH expanded guidance, which was completed in August 2002. This expanded guidance is to help in:

- planning for a mass casualty incident and the need for special considerations of NHS capacity, including infrastructure, hospital services and specialist support requirements;
- detecting clusters of unusual diseases. It also provides an algorithm for assisting decision making in determining if the illness is likely to be due to biological, chemical or radiological causes. This information is crucial in detecting covert releases and should be brought to the attention of clinicians, microbiologists and toxicologists;
- tackling overt and covert releases of specified biological and chemical agents. This information outlines key planning tasks that need to be carried out by hospitals in the event of overt release of specific agents and in the follow up of covert releases.

The Role of the Health Protection Agency (HPA): Emergency Response

6. Outbreaks of disease have the potential to cause disruption for communities on a large scale and present operational problems to the NHS. Because disease outbreaks can develop very rapidly - being prepared and emergency planning are essential components in minimising the impact on the public. Responding effectively means organisations working together to minimise the impact and achieving a return to normality as quickly as possible. The growing threat of global terrorism means that the HPA, which was established on 1 April 2003, needs to be prepared to deal with incidents that could involve biological materials.¹ This means new plans and new expertise. The NHS has a good track-record in responding to emergencies and over the last two years has been preparing for these new potential threats. In particular, this means that the HPA has been:

- building on the existing major incident plans.
- developing the infrastructure for surveillance and early recognition of events.
- continuing to produce guidance for health protection for these new hazards.
- identifying specific countermeasures and making sure they are available quickly.
- providing training and testing new plans.

7. The Agency's Emergency Division's role includes:

- Improving the speed and effectiveness of our overall response, both locally and nationally, in the event of any future incident or threat. This includes providing positive and authoritative messages about health protection measures in order to reduce public anxiety.
- Providing a central source of authoritative scientific/medical information and other specialist advice on both the planning and operational responses to major incidents and wider public health or other emergencies.

¹ The different divisions that make up the new Health Protection Agency were individually responding to these threats prior to April 2003. The strength of the new organisation, is that it will bring them together in a co-ordinated way. There will be integration across the divisions operating at local, regional, and national levels. It provides a single identifiable health protection organisation for the NHS, government, and other agencies.

Training: Counter-Terrorism Exercises

8. The UK's programme of counter-terrorism exercises is a vital part of the UK's work in resilience and contingency planning, as it allows us to test systems thoroughly, train frontline responders, and highlight vulnerabilities. Training exercises are an important part of counter-terrorism, as they ensure that the UK is prepared to respond to any kind of terrorist attack and that our counter-terrorism arrangements are tested. Of course, Government, the emergency services and others regularly train and practise their responses to all kind of major incidents, including natural disasters and accidents. However, the Home Office runs a programme of major exercises that specifically deal with terrorist scenarios.

9. The proportion of 'live' to simulated elements in each exercise varies according to the exercise scenario. Types of exercise include:

- 'Tabletop' exercises take place in a workshop or seminar setting. These are useful to test discrete elements of a response, or for scenarios that would greatly disrupt the public if run 'live' – such as an evacuation of a major city.
- Command post exercises involve setting up a real incident control room to co-ordinate responses, but will not involve much action at the scene of the incident.
- Full-scale 'live' exercises often run over several days and typically involve hundreds of participants. In a live exercise, for example, bomb disposal teams might physically make a dummy device safe, and police officers might cordon off a simulated contaminated area.

10. All exercises are fully evaluated and participants are given detailed feedback. The results inform our ongoing review of the UK Counter-Terrorism Contingency Manual – a classified document used by everyone involved in responding to terrorist incidents. The Home Office simulates three full-scale 'live' terrorist attacks and 12-15 'tabletop' or workshop exercises each year. Police forces lead counter-terrorist exercises, with Home Office support. Depending on the scenario, they can involve any, or all, of the following:

- government departments
- the emergency services
- the military
- local authorities and health providers
- scientists and technical specialists
- utility companies
- the security services

11. Exercises take months of planning to ensure realistic, challenging situations that involve as many agencies as possible and validate every aspect of our response.

Participants do not know the scenario before it begins. A single exercise can take several days, and include various kinds of incident or attack.

Public Information

12. The purpose of the publication *The Decontamination of People Exposed to Chemical, Biological, Radiological or Nuclear (CBRN) Substances or Material* is to provide strategic guidance on decontamination upon which all responding agencies can base plans and

Memoranda of Understanding (MOUs) for on-site management of CBRN incidents. It also provides advice on decontamination methods based on lessons learned from previous incidents and exercises and drawing on current research projects. As set out in the introduction, this guidance is intended to encompass all hazardous materials incidents, not simply the deliberate release of CBRN material by terrorists or states. It is intended to provide all those involved in the decontamination of people exposed to CBRN substances or materials with a common set of principles, using common terminology, and with a shared and agreed understanding of each others' roles and responsibilities.

13. Previous advice on CBRN and decontamination has been issued through individual emergency services, agencies or departments. The need now is to ensure that these strands are amalgamated and that procedures are aligned. The strategic guidance has been prepared with input from a wide variety of specialist and professional sources.

14. A CBRN release may quickly spread across a number of administrative and geographical boundaries, including the boundaries of the devolved administrations within the United Kingdom. Reinforcement and regional mutual aid will feature as a key consideration. Clearly, commonality of procedures and inter-operability of equipment is critical to the successful delivery of mass decontamination. This guidance has been produced with contributions from the devolved administrations and is for use across the whole of the United Kingdom.

15. This document should be read in conjunction with other national level guidance, e.g. *Dealing with Disaster* (and equivalent publications in the devolved administrations), departmental guidance and specialist publications such as the Home Office Counter Terrorism, Contingency Planning guidance manual. *Dealing with Disaster* (Revised 3rd Edition) collates the principles of co-operation which guide the multi-agency response to, and management and resolution of, a major incident. The revised 3rd Edition has been produced in recognition of considerable changes to the structure, practice, regulation and legislation in emergency planning in recent years. It is available at <http://www.ukresilience.info/contingencies/dwd/index.htm>. The CCS publishes up-to-date information on civil contingencies on the UK Resilience website: <http://www.ukresilience.info/home.htm>. Home Office advice can be found at: <http://www.homeoffice.gov.uk/terrorism/threat/info/index.html>.

16. The Public Health Laboratory Service provides advice to the public and health professionals at: http://www.phls.co.uk/topics_az/deliberate_release/menu.htm.

This website provides advice on range of biological agents that might be used in a terrorist incident; for example. *Interim guidelines for action in the event of a deliberate release of anthrax*; *Clinical evaluation and management of persons with possible inhalation anthrax*; and *Interim Guidance for the Investigation and Management of Outbreaks and Incidents of Unusual Illness: A Guidance for NHS Staff*. A recent addition to the list of advisory material includes a completed clinical training slide set. The Department of Health's Emergency Planning Coordination Unit has its own website at: <http://www.doh.gov.uk/epcu/cbr/intro.htm>.

Legislation: The Civil Contingencies Bill

17. The Civil Contingencies Bill, published on 19 June 2003, repeals outdated legislation such as the Emergency Powers Act 1920 and the Civil Defence Act 1948. The draft Bill, with accompanying non-legislative measures, will deliver a single legislative framework for civil protection in the UK. It will modernise the legislative tools available to government to deal with

the most serious emergencies, providing greater flexibility, proportionality, deployability and robustness. The framework will enhance existing regional resilience by delivering a new regional civil protection tier. A clear role for the regions in civil protection will ensure consistency of activity across and between the tiers, and set out clear expectations and responsibilities - from front line responders, through the regions to central government departments. At the local level, a two-tier duty will be introduced for local responders to codify existing best practice. This will clearly identify local responder roles and responsibilities within the area of civil protection, ensuring consistency and enhancing performance and communication. These improvements will deliver practical benefits and enhance the local response capability.

United States

Security of Select Agents at Bioscience Facilities

Biosafety vs. Biosecurity

- Biosafety
 - Objective: reduce or eliminate accidental exposure to or release of potentially hazardous agents
 - Strategy: implement various degrees of laboratory “containment” or safe methods of managing infectious materials in a laboratory setting
- Biosecurity
 - Objective: protect against theft or diversion of select agents
 - Strategies
 - Define risk by evaluating probabilities and consequences
 - Protect defined assets against defined threats
 - Apply a graded protection approach
 - Integrate security technologies and procedures
 - Impact operations only to the level required

Need to Secure Select Agents

- Aim of biosecurity is to mitigate BW threat at the source
 - Prevent terrorists or proliferant states from acquiring select agents from government, commercial, or academic facilities
- Securing select agents is an important element of comprehensive BW nonproliferation programs
 - Cannot prevent BW terrorism or proliferation
 - Must be augmented by other national mechanisms

Challenges to Securing Select Agents

- Dual-use characteristics
 - Valuable for many legitimate, defensive, and peaceful commercial, medical, and research applications
- Nature of the material
 - Living and self-replicating organisms
 - Used in very small quantities

- Cannot be reliably quantified
- Exist in many different process streams in facilities
- Contained biological samples are virtually undetectable
- Laboratory culture
 - Biological research communities not accustomed to operating in a security conscious environment

Biosecurity Cost Benefit Considerations

- Bioscience facilities are not unique repositories
 - Most agents can be isolated from nature
 - Many similar collections of agents worldwide
- Relatively few agents can be easily grown, processed, weaponized, and successfully deployed while maintaining virulence/toxicity
 - Very few agents used as a weapon could cause mass human, animal, or plant casualties
 - Not all agents equally attractive to adversaries
- Need a methodology to make informed decisions about how to design an effective and efficient biosecurity system

Biosecurity Methodology

- Qualitative risk and threat assessment is the essential first step
 - Process should include scientists, technicians, managers, security professionals, and law enforcement (counter-terrorism) experts
- Asset identification and prioritization
 - Consequences of diversion and adversary attractiveness
- Threat identification and prioritization
 - How would an adversary steal the defined assets?
- Risk and threat assessments establish design parameters and protection principles

Asset Identification and Prioritization

- Primary consequence
 - Loss could lead to national security event (bioterrorism)
 - Certain biological agents
- Secondary consequence
 - Loss could assist in achieving a primary consequence or access to a primary asset
 - Certain information related to select agents
- Tertiary consequence
 - Loss could affect operations
 - Certain facilities, equipment, etc.

Threat Identification

- Adversary categories
 - Insider with authorized access
 - Invited outsider(s) – visitor
 - Outsider(s) with limited access and system knowledge

- Outsider(s) with no access and general knowledge
- Collusion between an insider and an outsider
- What will the adversaries aim to do?
 - Steal agents, steal information, disperse agents, destroy/deface facility, steal equipment, etc.
- How will the adversaries perpetrate the event?
 - Alone or in a group? Armed or unarmed? Covert or overt?

Risk Prioritization

Generic Biosecurity Design Parameters

- Highest risk scenarios
 - Insider, visitor, or outsider with limited access attempting to steal select agents covertly
- High risk scenarios
 - Insider, visitor, or outsider with limited access attempting to steal select agent-related information covertly
- Medium risk scenarios
 - Small outsider groups that would aim to destroy or deface the facility
- Terrorist commando assault unlikely
 - Agents available elsewhere
 - Overt attack using force would signal authorities to take medical countermeasures

Generic Biosecurity Protection Principles

- Personnel Reliability
- Physical Security
- Information Technology Security
- Material Control and Accountability
- Material Transfer Security
- Program Management

Personnel Reliability

- Allow access only to those individuals who have
 - Legitimate need to handle select agents
 - Appropriate training in biosafety, containment, and security procedures
- Conduct background investigations on employees
- Establish visitor interaction procedures
 - Screening, badging, and escorting
- Report suspicious activity

Physical Security

- Implement systems to deter, detect, and respond to unauthorized attempts to gain access to select agents
- Establish graded protection areas with
 - Intrusion detection

- Access controls and transaction recording
- Alarm assessment capabilities
- Physical barriers and delay systems
- Law enforcement response capabilities

Material Control and Accountability

- Develop systems to document
 - What materials exist in a certain facility
 - Where they are located
 - Who is responsible for them
 - Who has access to them
- Avoid trying to apply quantitative material-balance inventory accounting principles

Material Transfer Security

- Document, account for, and control select agents when they are moving between protected areas within a facility
- Receive authorization and monitor external transfers between registered facilities before, during, and after transport

Information Technology Security

- Control access to sensitive information related to select agents
- Establish policies and implement technologies for handling, using, and storing paper-based, telephonic, photographic, and electronic media

Program Management

- Provide policy oversight and implementation of the biosecurity program
- Maintain documentation of
 - Security plan
 - Incident response plan
 - Security training program
 - Self-assessment and auditing program

Summary

- Necessary to take steps to reduce the likelihood that select agents could be stolen from bioscience facilities
- Critical that these steps are designed specifically for biological materials and research so that the resulting system will balance science and security concerns

China

Statement on Biosecurity and Oversight: Facilities

In order to strengthen biosecurity and oversight of the facilities involved pathogenic microorganism activities, China strictly administers the storing, carrying, shipping, using and supplying of medical microorganisms including various infectious agents, and the biosecurity of laboratories involved experiments with pathogenic microorganisms.

I. Relevant Regulations

China formulated the following relevant regulations and criteria:

- Law of the People's Republic of China on the Prevention and Control of Infectious Diseases (Adopted in 1989) and its Implementation Regulations (Promulgated in 1991)
- Measures of the People's Republic of China on the Administration of the Storage of Strains of Medical Microorganisms (Promulgated in 1985)
- General Guidelines of the People's Republic of China on Biological Safety in Microbial and Biological Medical Laboratory (Promulgated in 2002)

II. Storage of Strains of Medical Microorganisms

The storage of strains of medical microorganisms is under the centralized management and supervision of the bodies designated by the Ministry of Health.

The storage centres for the strains of medical fungus, bacteria and virus are established to supervise the selection, collection, identification, storage of above mentioned species, and study on their classification, identification and storage.

Specialized laboratories are established under the storage centers to supervise the selection, collection, identification, storage of the specialized species respectively, and study on their classification, identification and storage.

Japan

Japan's Facility Planning and Management to Maintain Safety of Pathogens Used Within

While Japan does not have a law that defines safety standards and physical protection requirements for facilities possessing pathogens and toxins in general, certain standards and requirements have been set forth in individual laws and regulations in relevant fields.

For public health security, for example, the Pharmaceutical Affairs Law stipulates that pharmaceutical production facilities using pathogens should meet plant and equipment standards to prevent the leakage of pathogens.

As for the laboratory containment standards, the WHO Biosafety Level (BSL) designation has been widely applied in most of the relevant laboratories in Japan. The risk assessment is done by each agent in laboratories. Thus biological agents are handled according to this assessment with

appropriate containment measures that meet the WHO requirements for BSL 1 to 3. The Guidelines for Recombinant DNA Experiments, which will be described later, classify genetically modified organisms (GMO) into containment level groups and set, for each group, detailed requirements for laboratory design and safe handling procedures of GMO. There are other guidelines on appropriate equipment and facilities for the safe use of DNA recombinants in industry, agriculture, forestry and fishery.

United Kingdom

Health and Safety: Biological Agents – Containment Issues

Introduction

- Risk assessment (performed by duty holder)
- Containment
- Protection

Risk assessment: key to managing safety

- Define and characterise the risk issue
- Examine the options and their merits
- Adopt decisions
- Implement decisions
- Evaluate effectiveness

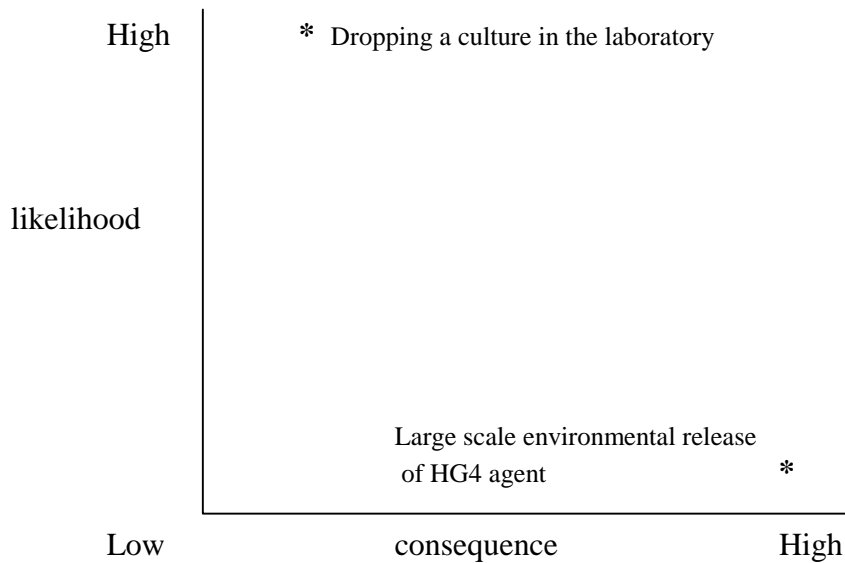
Five steps to risk assessment

- Identify hazards
- Decide who might be harmed and how
- Evaluate risks and decide if controls are adequate
- Record findings
- Review and revise if necessary

Classification of biological agents

- HG1 – unlikely to cause harm to human health
- HG2 – can cause human disease, might be a hazard to workers, is unlikely to spread to the community and there is usually effective prophylaxis or treatment available
- HG3 – can cause severe human disease, present a serious hazard to workers, may present a risk of spreading to the community, usually effective prophylaxis or treatment available
- HG4 - can cause severe human disease and is a serious hazard to workers, may present a high risk of spread to the community and no effective prophylaxis or treatment is available

Estimating risk



Containment

- The way in which biological agents are managed in the laboratory environment so as to prevent, or control, the exposure of laboratory workers, other people and the outside environment to the agent(s) in question
- Employee management and training
- Primary
 - Good microbiological practice
 - Air handling
 - Immunisation
- Secondary
 - Laboratory design
 - Standard operating procedures
 - Restriction of access
 - Safe disposal of waste
 - Microbiological safety cabinets

Containment level 2

- Working with HG2 agents requires a minimum of CL2
- CL2 must be used where there are uncertainties about the presence of HG2, HG3 or HG4 agents if the intention is not to deliberately propagate and concentrate such agents
- CL2 probably most commonly used containment level, is suitable for broad range of clinical, diagnostic and research work with biological agents, which although capable of causing disease, only present a low-to-moderate risk.
- Example organisms:
 - *Staphylococcus aureus*
 - *Legionella pneumophila*
 - *Shigella sonnei*

Containment level 3

- CL3 must be used if the employer knows or suspects that such a containment level is necessary even if there is no intention to deliberately propagate and concentrate
- CL3 must be used when it has not been possible to carry out a conclusive risk assessment but if it is clear that the activity might involve a serious risk for employees
- CL3 laboratories are highest containment laboratories in common use in UK
- Example organisms:
 - *Mycobacterium tuberculosis*
 - *Salmonella typhi*
 - *HIV*

Containment level 4

- CL4 must be used if the employer knows or suspects that such a containment level is necessary, even if there is no intention to deliberately propagate and concentrate
- CL4 laboratories are **highly** specialised laboratories
- Example organisms:
 - *Ebola virus*
 - *Lassa*

Containment measures

- Air handling
- Security and access
- Disinfection and disposal procedures
- Protective equipment and procedures

Microbiological safety cabinets

- Class I, II and III
- Operator protection factor
- Class III totally enclosed (usually confined to some HG3 and all HG4 work)
- Key issues:
 - Maintenance
 - Fumigation
 - Training for use
 - Factors affecting

Personal protective equipment

- Types
 - Gloves
 - Safety glasses
 - Lab coats
- Key issues
 - Last line of defence

- Storage
- Cleanliness

Bulgaria

On behalf of the Bulgarian Delegation I would like to present some brief information about our activity and existing regulations on national level about risk assessment, safety equipment and biosafety of the personnel working with biological agents – pathogens and toxins from different groups.

In Bulgaria in 1971, more than 30 years ago, was issued the first very detailed order by the Minister of Health about the requirements for the premises, the equipment and the personnel working with highly dangerous bacterial and viral pathogens. This document is modified and ameliorated during the years according to the contemporary achievements of the science and its current practice. The latest version of this order was made two years ago and now it is a very comprehensive and updated document that clearly determines all the obligatory requirements for laboratory work with dangerous pathogens according to the good laboratory practice and the guidelines of the WHO in this field in order to maintain a sustainable biosafety and to prevent the misuse and the spread of pathogenic microorganisms in indoor and outdoor environments including humans.

Speaking about the biosafety, last year in Bulgaria was issued a new special state regulation – State Regulation No. 4/October 2000- by the Ministry of Health and the Ministry of Social Affairs firmly endorsed by the National professional medical organization and the trade unions about the occupational biosafety of the personnel working in contact with biological agents. This regulation with very well defined provisions clearly and in detail determines:

- The methodology of risk assessment and its practical realization even on the lowest laboratory level in the country;
- The mandatory activities and practical measures which have to be taken by the laboratory, hospital, research center, bioindustry managers to prevent the personnel, the laboratory premises and outdoor environment of transmission and contamination with different hazardous biological agents. Special attention is paid in this document on the use of the safety equipment which has to be checked regularly by qualified engineers.
- Very important mandatory requirement is the use of convenient personal protective equipment and the regular medical observations including some laboratory test of the personnel working in these laboratories which is realized on the basis of a special health monitoring program individualized for each particular case;
- The contemporary classification of all microbial, viral, fungal and parasitic pathogens divided into the well known four groups and the concrete requirements for work with each of them from the point of view of biosafety and biosecurity.

Briefly I dare to state that this document dealing with the occupational biosafety and biosecurity is a good base for stable and reliable work in this field in our country in compliance with the best international standards.

United States

Pathogen Containment, Disposal, Storage, and Custody

Physical Containment and Laboratory Waste

Physical Containment of Organisms/Toxins

Basic features

- Facility Design
- Engineering Controls
- Personal Protective Equipment
- Administrative Controls

Biosafety Levels

Establish the minimum features required for containment in

- Biosafety Level 1
- Biosafety Level 2
- Biosafety Level 3
- Biosafety Level 4

Establishing Basic Physical Containment

- Limiting dispersal within the laboratory
- Primary barriers (Biosafety Cabinets and Chemical Fume Hoods)
- Lockboxes, access controlled refrigerators or freezers
- Demarcation of areas specifically assigned for manipulation of organisms/toxins within shared laboratories
- Limiting entrance of personnel to the laboratory

Controlling Waste

Considerations:

- Organism/Toxin Inactivation
- Organism/Toxin Disposal
- Record keeping
- Security
- Quality Control Systems

Organism/Toxin Inactivation

- Inactivation Standard
 - Biological Toxins: No measurable toxic effects
 - Microbes: sterilization vs high level disinfection

- Inactivation Methods
 - Will vary based on organism/toxin
- First step in Inactivation: Risk Assessment
- Methods may include:
 - Steam and pressure
 - Chemical Inactivation
 - Incineration
 - Combination new technologies

Organism/Toxin Disposal

- Accountability includes all handling steps through final disposition
- Once inactivated organism/toxin can be placed in routine biomedical waste
- Incineration or other disposal methods

Recordkeeping

- Accountability of materials is key
 - Who possessed the organism/toxin?
 - Who destroyed the organism/toxin?
 - When, where and how was organism/toxin destroyed?
 - Volume of material destroyed?
- Maintaining a secure logbook

Security

- Records are sensitive information
- Organisms/toxins are still sensitive until final disposition
- Maintain security procedures until final disposition

Storage and Custody of Agents

Storage of Select Agents

- Access to storage areas is controlled
 - Freezers are kept locked when not in direct view of approved staff
- Inventory procedures must be documented:
 - Education and experience of individual with access
 - Physical security
 - Cybersecurity

Access to Storage Areas

- Storage areas must be separate from public areas of building
- Restricted to personnel with approved security risk assessments
- Escorted access must be documented: who, when, by whom

Inventories

- Access limited to personnel with approved security risk assessments
- Procedures for reporting loss, theft, or release of select agents/toxins or alteration of inventory records
- Records are accurate and current

Inventory Information

- Name, characteristics, and source of select agent or toxin
- Quantity, volume, or mass destroyed or disposed of and when
- Quantity possessed and used or destroyed (toxins only) and when
- Quantity transferred: when, to whom

Custody Issues

- Security plan details custody procedures, including provisions for:
 - Loss/compromise of keys, passwords, etc.
 - Reporting of suspicious/unauthorized personnel
 - Control of access to storage containers
 - Ensure all approved personnel are properly trained
 - Reviewed/updated annually
 - Document intra-facility transfers
 - On-site disposal of select agents or toxins

Republic of Korea

One of the main themes at this meeting seems to be how to transfer our focus from bio-safety to bio-security or to emerge both concepts in our national systems.

The concept of bio-security is more challenging than bio-safety in the sense that the consciousness or advertent activities of men and women may cause much more problems than the unconsciousness or inadvertent activities, and that more variables need to be taken into account in the former than in the latter.

Again in this area like other areas of our concern, balancing is one of the key elements to keep in mind in reviewing existing legislation or adopting new legislation. In fact, especially to some laboratories with limited resources, the measures for bio-security might be quite burdensome, and to these laboratories the benefit of security can be more invisible than that of safety. Thus in instituting and implementing bio-security we have to take into consideration not only the specific circumstances surrounding the concerned facilities but also the resources and burdens as well as the existing mechanism for bio-safety and the overall status of national security.

China

Statement on Biosecurity and Oversight: Administration over Microorganisms

China's practice on the classification and administration of medical microorganisms is as following:

I. Classification of Strains of Medical Microorganisms

Classification of strains of medical microorganisms depends on their pathogenic capacity, including the following factors:

- Possibility of laboratory infection
- Possibility of contracting a disease after infection
- Symptom and recovering
- Whether it is mortal and whether there exists effective means of preventing laboratory infection
- Whether the laboratory infection can be prevented through general microorganism handling procedures
- Whether the pathogen was found and spreading in China before
- Immunity of human

China has established four categories of strains of medical microorganisms based on their pathogenic capacity. The first group contains the most dangerous pathogens. The second and the third group contain the less dangerous ones. The fourth group contains mainly biological products, attenuated and avirulent strains for vaccine production.

II. Administration of Strains of Medical Microorganisms

China puts in place detailed requirements for storage of different kinds of strains of medical microorganisms on storing equipment, technical measures, biosecurity measures and physical protection.

China has classified management based on the classification of strains of medical microorganisms on supply, limits of use, approval of use, application, posting and package.

China puts in place specific requirements for the laboratories involved strains of medical microorganisms experiment, based on the use and classification of strains of medical microorganisms, on laboratory levels, personnel protection, disposal and destruction of the used strains of medical microorganisms.

Wednesday 27 August 2003

Bulgaria

I would like to just briefly share with my distinguished colleagues from the Member States some aspects of our activities in Bulgaria on a national level for surveillance and control over the use and spread of pathogenic microorganisms with importance for public health.

In Bulgaria, we have more than 200 microbiological, virological, mycological and parasitological laboratories in the public and private sectors working in the diagnostic or research fields. All these laboratories are under constant control and monitoring by the Ministry of Health. This activity is organized and performed by a special body, which consists of a group of the best specialists in the country in the above-mentioned specialities – the so-called National Consultants appointed by the Minister of Health.

This body, on the basis of the National Reference Laboratories for different pathogens, which belong to the National Centre of Infectious and Parasitic Diseases (NCIPD), practically forms the National Review Body overseeing potentially dangerous activities, risk factors, licensing the laboratories, etc., and has all the information about the work carried out in them based on the official guidelines, regulation and laws. All these laboratories are obliged according to our legislation to take part in the National system of external laboratory quality control and quality assurance of their activity. But before saying some words about this National system I will explain briefly the procedure of licensing of the microbiological laboratories.

The Ministry of Health has officially approved National Standards for each of the following specialities: microbiology, virology, mycology, parasitology. These standards actually represent the foundation for performing of the activities in these medical specialties on the basis of GLP (Good Laboratory Practice). These standards determine clearly and comprehensively the compulsory requirements for the laboratory premises, the laboratory equipment, the qualification and the expertise of the staff and the used methodology for identification of the different bacterial or viral strains. Practically, this means that we are informed about the strains, which are going to be used in each particular laboratory before the activity starts, and on the basis of their capacity the laboratories are divided into three levels. Only the so-called National Reference Laboratory for very dangerous pathogenic bacteria and viruses, which belongs to the NCIPD, is allowed to work with microorganisms from group 3 and 4. The staff of this laboratory is strictly selected. The main requirements are that the doctors, the biologists and the technical assistants should have speciality in microbiology or in virology, which means to be officially licensed and to have minimum 3 years of practice in the respective fields. They are appointed after signing a special declaration that they are very well informed about all documents, regulations and methodological approaches with respect to the work with very dangerous pathogenic agents.

But what is more important in respect of our discussion is the above-mentioned National system of external laboratory control of quality and quality assurance, organized and carried out by the National Reference Laboratories to the NCIPD and the above mentioned body of National Consultants. According to this system, all laboratories in Bulgaria are obliged to take part twice a year in this control mechanism in order to assess in detail their practical activity and capability and only after successful covering of all criteria for good identification of test materials – bacterial, viral strains or human sera – they receive a special certificate giving them the right to

continue their work. For each laboratory the NCIPD maintains a file with all the details in terms of premises, equipment, staff, used methodology, the characteristics of the studies microorganisms, the characteristics of the studies material, the quantity and type of isolated strains, etc. Thus, we have on the central level – in the NCIPD to the Ministry of Health – the full information about what is going on in the country in the field of laboratory work in microbiology, virology, mycology and parasitology.

China

Statement on Biosecurity: Personnel Security and Management

Personnel working with pathogenic microorganisms are usually creators of accidents and victims of such accidents at the same time. China has adopted the following measures to ensure the safety of laboratory personnel and prevent the accidental leakage of pathogenic microorganisms.

1. Personnel Protection and Safety Equipment.

- 1.1 Personnel working in BL3 laboratories must receive training on biosecurity operations and pass the relevant exams before they can get qualifications for their job.
- 1.2 Serum samples should be taken for future reference from personnel working in BL3 laboratories before their first entry into the laboratory. Personnel should be vaccinated according to the category of the pathogenic microorganism if the vaccine is available. In case the vaccine is not available, emergency medical treatment drugs should be prepared.
- 1.3 All operations concerning contagious materials should be done within the biological safety cabinet II. In case such operations have to be done outside the biological safety cabinet, the operator shall wear suitable personal protection equipment, such as laboratory suit with positive pressure. Physical protection not only includes the facility, equipment of high containment laboratory and personal protection equipment, but also includes patient transfer isolator, ambulance with negative pressure and HEPA exhaling ventilator, high containment ward with negative pressure. These are aimed at the prevention of pathogenic microorganisms spread so that no harm will be done to man and the environment.

2. Entry and Leaving Procedures for BL3 Laboratories.

Access control is imposed in BL3 laboratories. Anyone who is highly fatigued, pregnant, with wound on hand or other exposed part of the body, or has skin diseases is not allowed to work in BL3 laboratories.

When entering BL3 laboratories, one should first enter the first change room, change into working cloth and shoes specially designed for use in BL3 laboratories. Then he can enter the second change room, wear the isolation cloth, hood, mask, protection glasses, shoe covers and gloves. Only then can he enter the operational area and start his work.

The sequence is just the opposite when leaving the BL3 laboratory. Before entering the second change room, one should take off the hood, mask, isolation cloth, shoe covers and gloves in the

assigned area and leave all these in a special container. He can take off the working cloth in the second change room and change into his own clothes in the first change room.

Clothes and other reusable articles should be decontaminated before washing.

3. Supervision and Inspection System.

Laboratory director is directly responsible for laboratory safety and is obliged to provide systematic training on operations for his subordinates. A security officer should be appointed by him to supervise any inappropriate operations or misconduct of laboratory personnel. The security officer is also responsible for personnel safety training and experimental safety. He should consult the biosecurity board, which is consisted of experienced experts, on new regulations and rules, new experiment programs as well as accident prediction. This board is also entrusted with technical guidance on laboratory safety. The superiors of the laboratory should periodically check the implementation of the safety rules. The facility personnel safety should be guaranteed by this multilayer supervision and inspection system where responsibilities are clearly distributed.

The oversight and check of high containment laboratories should not only rely on biosecurity officers, but also on intelligence computer control system, through the vigilance, adjust and control function of which can the balance of negative pressure be maintained in the laboratory and HEPA be effective filtered.

United Kingdom

Personnel & Handling – Training And Continuing Education

As explained in the UK paper circulated at this experts meeting, “*The Design of National Mechanisms to Maintain the Security and Oversight of Pathogenic Microorganisms and Toxins*”, the Biological Agents Directive (2000/54/EC) outlines the requirements relating to the protection of workers from risks related to exposure to biological agents at work. This Directive is implemented in the UK via the Control of Substances Hazardous to Health (COSHH) Regulations, which are issued as a Statutory Instrument under the Health and Safety at Work Act etc 1974. It follows, therefore, that COSHH is the main UK regulation dealing specifically with training for work with biological agents, including dangerous pathogens.

In UK law the general responsibilities of employers for safety training and supervision is enacted through the Health and Safety at Work etc Act 1974. The Management of Health and Safety at Work Regulations further clarify these responsibilities. Regulation 12 of COSHH, however, places the specific requirement on employers to provide information, instruction and training for those who may be exposed to biological agents.

Further guidance for organisations in the interpretation of their responsibilities in this area is provided by the Advisory Committee on Dangerous Pathogens (ACDP) through its publication “*The Management, Design and Operation of Microbiological Containment Laboratories*”, prepared in consultation with the UK Health and Safety Executive (HSE). The ACDP is appointed by, and advises, the UK Health and Safety Commission and Ministers in the Department of Health. It has produced several other guidance documents on specific aspects of

working with biological agents and on working with specific agents (e.g., “*Transmissible Spongiform Encephalopathy Agents: Safe Working and the Prevention of Infection*”). These documents help employers formulate organisational policy from which much training stems. Further details about the ACDP, its composition, activities and publications can be found on the HSE website at: <http://www.hse.gov.uk/aboutus/meetings/acdp/index.htm>.

The basic training requirements reflected through the COSHH regulations are to ensure employees understand:

- the hazards associated with the work they are doing (that is, they must know what substances they could be exposed to, and what risks are created by such exposure);
- how their work exposes them to the hazard, and how the risks to them are being controlled;
- the fundamentals of how the control measures work (including containment facilities and equipment, and personal protective equipment and clothing) and how to recognise defects in these control measures
- the emergency procedures to be followed (that is, what to do if something goes wrong).

A large amount of information, therefore, needs to be imparted to staff members to fulfil these responsibilities, and many organisations have the fundamentals written into formal policy documents such as Codes of Practice, and into risk assessments directly associated with the work itself. Clearly though, it is not enough merely to hand these documents over to staff members and expect them to absorb and understand all the information. So most organisations use formal training courses to introduce employees to the principles.

Formal training should also be supplemented with direct supervision. Organisations take different approaches to supervision but one of the most effective methods is one-to-one supervision, which should progress at the pace of the trainee. This is time-consuming and therefore relatively expensive for the organisation, but is more likely to result in a high level of understanding if performed well.

Various strategies can be employed by an organisation to ensure quality training, supervision and assessment of competence takes place. The following may be considered examples of good practice (but not necessarily the legal requirement) drawn from the experience of laboratories working with dangerous pathogens in the UK:

- The competence of a staff member should be regularly reviewed by an organisation.
 - Assessment of the competence of staff, and their training, should not be a one-off event. Changes in work practices or procedures, legislation or the understanding of the risk of a particular agent or procedure will require refresher training for employees.
 - In addition, competence can decline if skills are not used regularly, so supervision should be flexible and match the demands of the individual.
 - Even highly experienced and competent staff may require some level of periodic supervision to ensure that standards are being met consistently.
- Formal training should be used to expand on policy documents.

- Policy documents, often used as a framework for training, generally include the key topics drawn from legislation and guidance documents, such as the operation of the facilities, primary and secondary containment, waste management, emergency procedures, disinfection, sterilisation and fumigation.
- Formal training expands on these areas to include more interpretative areas such as microbiological risk assessment, and the minimisation of risk associated with particular work practices.
- Training, supervision and assessment is structured and tiered according to experience and biological hazard level.
 - Before new entrants undertake any laboratory work, an appropriate supervisor or mentor should be assigned to them by line management. New staff intending to work in biological containment level 2 laboratories, or above, are first trained in the fundamentals of working in microbiological areas (including good microbiological practice and containment).
 - Following “basic” training, staff should be allocated an experienced supervisor to provide one-to-one training and supervision. This immediate supervision is the key component of a safe working policy - effective supervision forms the bridge between the theoretical training and the acquisition of practical experience.
 - Prior to being considered for work in level 3 laboratories, all staff must have undergone a minimum period of satisfactory working at level 2, during which they will have been assessed for the skills and temperament for level 3 work. For new staff this period may be of the order of 12 months. For staff with a minimum of 12 months level 2 experience gained elsewhere, 3 months may be acceptable. For staff with previous level 3 experience, an assessment may be made over a 1 month period.
 - Personnel must be over the age of 18 to work at containment levels 3 and 4.
 - As training progresses, the competence of the person will be assessed by the supervisor and the level of supervision adjusted as appropriate. Direct supervision (one-to-one with a mentor) may be successively superseded by indirect supervision (mentor generally available), and then a “buddy” system, as competence is established through experience.
 - Formal reviews of competence and the level of supervision required will be documented on the individual’s training record.

It must be recognised that some members of staff may not be suited to the level 3 or 4 working environments. Staff should be encouraged to express any concerns, and if a supervisor believes that the person is not suitable for work at a high level of containment, they should discuss the situation with the individual and other appropriate members of staff. Extra training may be required, or indeed the individual may be withdrawn from the environment.

A clear understanding and implementation of health and safety regulations through training and education is essential for any organisation working with dangerous pathogens and toxins. The organisation has a duty of care to its employees, as does the government to its citizens, to ensure

that people are not exposed to dangerous biological agents – especially as a result of inadequate working practices.

Ukraine

Safety measures for personnel working with pathogenic microorganisms in Ukraine

The issue of biological safety in Ukraine is regulated by the national State sanitary rules ("Rules of Organization and Safe Work in Laboratories (Divisions) of Microbiological Profile" 9.9.5-080-2002 and "Safety of Work with Microorganisms of I-II Groups of Pathogenic" 9.9.5-035-1999), which I mentioned in my presentation on August 26.

Besides them we have there a number of additional measures which ensure safety of personnel.

- Every laboratory has its own internal work regulations in accordance with the safety procedure with the pathogenic microorganisms used in the laboratory.
- Every personnel have exact functional obligations with the order of interchangeability at work.
- Specific regulations are developed with regard to action of personnel in case of various accidents (working with biological, chemical and physical agents).
- Person in charge of development and implementation of these regulations is the head of laboratory.

Professionalism of personnel is important. One of the forms in Ukraine to verify correspondence of personnel is giving them specific tasks and specialized tests. Program of further training of personnel is determined taking into account the results of these testing.

United States

Training and Training Methods

Personnel Training: Who needs to be trained?

Training Program

- Training content should include;
 - Information pertinent to the organism/ toxin being used
 - General and specific security concepts
 - Containment concepts
 - Laboratory safety
 - Waste disposal
 - Emergency response
- Provide a training manual for use as future reference
- Documentation of training program should include the program content, date training was provided, and the results of any testing administered

Continuing Training Programs

Continuing training programs should include:

- Review of facility rules and procedures with particular emphasis on policy changes.
- Case study exercises on practices and ethical issues.
- Any changes in national laws or other implementing instruments.

Training Methods

Considerations:

- Number of personnel to be trained
- Geographic location of personnel/laboratories
- Number of organisms/toxins and the complexity of the program
- Requirements for refresher training

Training Methods

- “One-on-One” training
- Web-based training
- Regional Conferences

Training Program: Classroom Setting

Advantages

- Very small groups (1 instructor to 1-3 students)
- Provides for rapid, intense information delivery
- Provides for immediate student feedback and a period of questions and answer
- Flexible and adaptable
 - Can easily be tailored for different laboratory needs

Web-based Training

Advantages

- Can be tailored to different work environments
- Can be completed at a convenient time for personnel
- Can easily be updated
- May be used for testing after a classroom training experience
- May provide advantages for annual re-training after an initial classroom experience

Regional Conferences

- May provide some benefits in refresher training as an adjunct to location-specific training
- Allows smaller entities to combine training resources
- Enables personnel to establish a professional network

- Allows personnel to gain knowledge about a variety of working environments
- Provides an broader opportunity for inter-active problem-solving

Romania

GMP: Biosafety/Biosecurity

What is GMP?

- GMP = a system of principles and requirements of national and international regulatory mechanisms governing the production, validation, marketing and sale of pharmaceutical and biological products (vaccines)
- GMP = a system controlling human medicinal and veterinary products
- Regional and international harmonization of quality assurance and quality control
- GMP = 'give me paper'

GMP – Regulations

- European Community Directives
- 1965 – 65/65/EEC – regulating the marketing of pharmaceuticals in EC
- 1975 – 75/318/EEC; 75/319/EEC – harmonization of the regulatory system in EC
- 1988 – European Commission = compliance with principles of GMP - compulsory within European Community
- 1989 – Guide to Good Manufacturing Practice for Medicinal Products
 - 1st Ed 1989
 - 2nd Ed 1991
 - 3rd Ed 1998 (with 14 additional annexes)

GMP – Principles (10 Commends)

- Write step by step operational procedures and work instruction
- Follow written procedures and instructions
- Document work
- Validate work
- Design and construct facilities and equipment properly
- Monitor facilities and equipment
- Define, develop and demonstrate job competence
- Protect against contamination
- Control components and product related process
- Conduct planned and periodic audits

GMP Essential Requirements

Refer to:

- Quality management
- Personnel

- Premises and equipment
- Documentation
- Production
- Quality control
- Contract manufacture and analysis
- Complaints and product recall
- Self inspection

GMP Documentation

Permits to control:

Used organism

- Type
 - Natural
 - Genetic modified
- Source
 - Domestic
 - Imported
- Quality
 - Certified
 - Capabilities
- Biologic/antigenic properties

Spaces/facilities

- Dedicated: rooms sizes, air control decontaminations
- Safety condition for:
 - Product
 - Personnel
 - Environment

Equipment

- Type – technical characteristics
- Capacity
- Safety performances for:
 - Product
 - Personnel
 - Environment

Processing

- Reagents – origin, quality
- Batches – size, number
- Safety/control procedures
- Quality requirements

Austria

Cooperation with National and International Agencies: NBC-related Training of Security Personnel

1. Introduction

The events of autumn 2001 in the USA led to an increase of sensitivity of the population and all the potentially involved ministries, agencies and organizations for the threat of terrorism with biological and/or chemical weapons. The Austrian Armed Forces (AAF) and, within it, the NBC-Defence is the support element tasked to address the effects of NBC-weapons on the population as well as to assist military and civilian victims of such weapons and/or Toxic Industrial Materials (TIMs), also called ROTA (Releases Other Than Attack) Agents.

2. Civil protection in Austria and the responsibilities of the AAF

According to the Federal Defence Act §2, all federal institutions as well as institutions and organizations of the provinces and municipalities have the authority to request the assistance of the AAF within their respective area of responsibility. As there is no specialized Civil Protection Unit in Austria, the AAF have repeatedly been requested as experts for inter-ministerial assistance in their quality as experts for training purposes. Within the AAF, the specialists of the NBC-Defence have the required competences in dealing with all kinds of NBC-weapons and hazardous substances and have therefore been tasked several times with such duties.

3. Content and aims of training

The following general training contents have been taught in different intensities throughout the various training sessions:

- Background information about the use of biological and chemical weapons.
- Basic knowledge about biological and chemical weapons and Toxic Industrial Materials (TIMs).
- Methods of individual protection and the necessary equipment.
- Behaviour and code of conduct towards such weapons and materials.
- Possibilities and equipment of the NBC-Defence of the AAF.
- Cooperation with the AAF.
- Experiences of the different operations of the NBC-Defence troops.

4. Past and current training

On the legal basis of the abovementioned inter-ministerial assistance, the following training sessions have recently been conducted by the AAF/NBC-Defence:

Sept./Oct. 2001: Ministry of Interior (MOI) and Vienna International Airport Society

Evaluation of the Standard Operations Procedures (SOPs) and Contingency Plans for NBC threats by experts of the AAF NBC-Defence School, in cooperation with the Security Personnel and the Fire Fighting Division of the Vienna International Airport.

Oct. 2001: Organisation for Security and Cooperation in Europe (OSCE)

Training for security personnel by experts of the AAF NBC-Defence School: code of conduct when receiving letters or parcels that might contain hazardous material or substances.

Autumn 2001: MOI and Ministry of Social Security and Generations (MSSG)

Organized by the Operations Department of the MOD, experts of the AAF NBC-Defence School gave information about and introduction to the then current situation with respect to biological weapons. The audience consisted of the Directors of the Provincial Health Authorities and the Heads of the Provincial Security Divisions.

Oct. – Dec. 2002: MOI

Preparation of standard training material, "Biological and Chemical Weapons", by the NBC-Defence School in order to conduct the following training, held by the NBC-Defence Officers of the Provincial Military Commands:

- Training for officials and officers of the police and gendarmerie on federal and provincial level.
- Lowest level of the trained officials and officers: police and gendarmerie command posts at the different districts in the nine provinces of Austria.
- Only in Vienna, around 20 training sessions have been held to cover a maximum of officials and officers of the police.

Winter/Spring 2003: Ministry of Foreign Affairs (MFA)

Target group of the training was the personnel of Austrian Embassies worldwide and especially in crisis regions most likely to be hit or to be affected by the release of biological and/or chemical weapons. So far the training was conducted in two different ways:

- The personnel of the Austrian Representations (Embassy and Commercial Section of the Embassy) plus all voluntary expatriates in Kuwait and Saudi Arabia have been visited by specialists of the AAF NBC-Defence.
- As part of the regular Consular Conferences for selected personnel of all the Austrian Embassies at the premises of the MFA in Vienna, the members of this conference have been invited for the first time for a one-day training to the NBC-Defence School of the AAF.
- The primary aim was the introduction to the NBC gear and its use and the introduction to necessary and helpful methods of individual protection.

5. Lessons learned

The provided and conducted training sessions have all been very well accepted by the trainees. This was especially evident by the active participation and the many questions asked.

The question of the protection against NBC weapons for children and babies was, especially for those Austrians living and working with their families in crisis areas and war- or warlike-scenarios, very important. As such protection equipment is not used by the military, the AAF

could only refer to a number of suppliers. Adults working at Austrian Embassies in crisis regions are supplied with the standard NBC protection gear of the AAF.

Austria

Training Concept for Military and Civilian Personnel: ROTA (Releases Other Than Attack)

1. Introduction

The threat of non-military nuclear, biological and/or chemical hazards is constantly increasing. A situation might result in the release of hazardous material through accidents of other incidents, such as:

- partly of completely destroyed technical installations;
- accidents in connection with the transportation of hazardous materials; and
- installations susceptible to interference; as well as
- environmental contaminations (of the past),

deriving from industrial, commercial, medical, military as well as private surroundings.

The technical term of "Toxic Industrial Materials" (TIMs) describes toxic and/or radioactive substances in solid, liquid or gaseous state. In reference to the classical military terminology of the NBC-Defence, we are also talking about "Toxic Industrial Radiologicals" (TIRs), "Toxic Industrial Biologicals" (TIBs), "Toxic Industrial Chemicals" (TICs) or, in a more general term, about "Releases Other Than Attack" or ROTA.

The release of such substances is usually handled by civilian organizations, agencies or task forces. During international military operations such civilian institutions are often not operable and the military has to take necessary responsibilities to protect their forces.

2. Civil protection in Austria

Civil protection is the summary of all the precautions taken, which should enable the population to survive difficult and dangerous situations of any kind. It covers all the humanitarian activities necessary to cope with emergencies and special crisis situations as well as the precautions to be taken in order to withstand natural disasters and/or industrial accidents. Civil protection is defined by the National Civil Defence, one of the four pillars of the Austrian National defence, and requires precautions by:

- authorities and
- task forces, as well as
- all the citizens in their private surroundings.

According to the Federal Defence Act §2, all federal institutions as well as institutions and organizations of the provinces and municipalities have the authority to request the assistance of the Austrian Armed Forces (AAF) within their respective area of responsibility. Within the AAF, the specialists of the NBC-Defence have the required competences in dealing with all kinds of NBC weapons and hazardous substances.

3. Austrian NATO/PfP involvement

Based on the Kosovo experiences, the need for an intensified ROTA education was defined during the annual NATO/PfP "NBC Working Group Training" of the year 2001. In the aftermath, two members of NATO School SHAPE came to the AAF NBC-Defence School in order to create a coarse concept of such a training. This was the basis for an AAF internal training concept (see para 4) for all troops, which shall be implemented by the end of 2003.

4. Training and further education in the AAF

The threat by non-military NBC hazards requires an appropriate training of all ranks involved in such operations. The different levels of command must be trained according to their responsibility not only to increase their sensibility but also their general knowledge about TIMs. The subject-specific training in the AAF is conducted in three different levels:

BASIC-degree: the trainees should obtain a basic knowledge about non-military hazards and TIMs and learn about the necessary steps for individual protection.

COMMAND-degree: the responsible commanding officer should be able to gain all information necessary about non-military hazards and TIMs for the protection and – if necessary – the evacuation of his troops and/or the population concerned by the incident.

EXPERTS-degree: the highest level of training with the aim of an appropriate identification of non-military hazards and TIMs to inform the commanding officer correctly, the higher commands and the authorities about the immediate and long-term threats and dangers evoked by the released substance (liaison to specialists and scientists).

The course comprises two modules (basic and advanced) of one week and will be held once a year.

- Basic course: lessons, syndicate work, presentations as a part of a "real" scenario.
- Advanced course: discussions, map exercises, field and command post exercises.

5. Curriculum of the EXPERTS-degree

Upon completion of the course, the students will be able to:

- describe the nature of ROTA risks,
- describe the characteristics and effects of selected TIMs,
- demonstrate the procedures for the determination of ROTA hazard areas,
- identify possible sources of TIM-related information such as legislation, databases, models, publications (Emergency Response Guidelines – ERG),
- explain the importance of pre-deployment hazard analysis,
- describe the requirement for liaison with civil authorities, agencies and assets,
- describe the capabilities of sampling and identification teams,
- provide timely and accurate advice to the commander on ROTA incidents, and

- plan the response within the capabilities and competences of the available personnel and equipment (detection, protection, decontamination means).

6. Target groups for the ROTA EXPERTS-degree training

In April 2003 the first EXPERTS-degree course has been organized and held by the Austrian NBC-Defence School. It is part of the Partnership Working Program (PWP) and will be held annually. The PWP defines and integration of at least 50% international military and civilian as well as national civilian participants. This integration should reach governmental and non-governmental agencies and task forces equally.

Argentina

ADMINISTRACION NACIONAL DE LABORATORIOS E INSTITUTOS DE SALUD (ANLIS) DR. CARLOS MALBRAN

La misión primaria de la Administración Nacional de Laboratorios e Institutos de Salud "Dr. Carlos G. Malbrán" (ANLIS) es entender en las políticas científicas y técnicas vinculadas con su competencia y promover, aprobar y evaluar los proyectos de los institutos y centros de su dependencia, desarrollando y coordinando acciones de prevención de la morbilidad causada por enfermedades infecciosas y enfermedades de riesgo con base genética o nutricional, por sí o por proyectos de capacitación y consultoría, en cooperación con unidades del Ministerio de Salud o de los Estados Provinciales y con otras organizaciones nacionales o internacionales.

Las principales acciones que se proponen llevar a cabo durante el año 2001 son:

- Desarrollar y promover el conocimiento de las características biológicas de los virus, bacterias, hongos y parásitos como agentes etiológicos en patologías humanas, sus vías de transmisión y su diagnóstico.
- Priorizar las actividades de investigación, producción, diagnóstico y formación de personal, dirigidas a las enfermedades controlables en la próxima década (Chagas y Lepra), a las enfermedades emergentes, re-emergentes o de importancia exacerbada, con el trabajo de las redes de laboratorio, en el marco de la protección de la salud del niño y el adolescente, la mujer, el trabajador y el anciano, exigiendo eficiencia en el uso del recurso y brindando seguridad biológica y laboral a los trabajadores y a la comunidad.
- Planificar y organizar la producción de biológicos, vacunas, sueros y reactivos diagnósticos destinados a la prevención, tratamiento y diagnóstico de enfermedades.
- Realizar estudios, investigaciones operativas y monitoreo de los parámetros salud-enfermedad de la población a través del diagnóstico epidemiológico, promoviendo la participación comunitaria como actividad conjunta a la que desarrolla la Dirección de Epidemiología en los brotes y epidemias.
- Determinar la distribución de enfermedades regionales producidas por la malnutrición de la población, determinando los mecanismos causales, para promover su solución y orientar los servicios de salud en la aplicación del Plan Alimentario Nacional.

- Realizar las correcciones necesarias destinadas a mejorar la planificación, programación y control de gestión, la definición de políticas y prioridades estratégicas y de recursos humanos, la descentralización de los Institutos y el direccionamiento estratégico en el marco de las nuevas condiciones tecnoproductivas locales e internacionales.
- Intensificar las condiciones de bioseguridad en los laboratorios de trabajo de los institutos a fin de minimizar el grado de peligrosidad de los mismos.
- Intensificar el trabajo de la Red Nacional de Laboratorios, ejecutando acciones orientadas a la capacitación, utilización de manuales, control del diagnóstico y transferencia de nuevas tecnologías.

INVESTIGACION, DESARROLLO Y SERVICIO EN INFECCIONES BACTERIANAS, MICOTICAS Y VIRALES

INSTITUTO NACIONAL DE ENFERMEDADES INFECCIOSAS AGUDAS

El Instituto Nacional de Enfermedades Infecciosas realiza una actividad referencial. En él se llevan a cabo doce grandes proyectos científico-técnicos de patologías infectocontagiosas que incluyen etiologías bacterianas, micóticas y vírales.

Las actividades de servicio contemplan el diagnóstico referencial que incluye el control de calidad del diagnóstico microbiológico, la producción de reactivos patrones (referenciales) y la capacitación de recursos humanos estratégicos.

Las actividades de investigación están orientadas al conocimiento fenotípico y genotípico de los agentes infecciosos, caracterizando las cepas que circulan en el país, su grado de patogenicidad y la resistencia a los antimicrobianos. Desarrolla, adapta y transfiere nuevas metodologías para el diagnóstico y la producción de reactivos diagnósticos.

Como laboratorio nacional de referencia trabaja en redes con el resto del país, a fin de asegurar la calidad del diagnóstico, contribuir a la vigilancia de patologías comunicables, de infecciones nosocomiales y a la aparición de nuevos patógenos o de situaciones diferentes que impliquen cambios de conducta hacia el tratamiento o implementación de acciones de prevención y control.

INVESTIGACION, DESARROLLO Y SERVICIOS EN VIROSIS HUMANAS PRODUCCION DE VACUNAS CONTRA FHA

INSTITUTO NACIONAL DE ENFERMEDADES VIRALES HUMANAS DR. JULIO MAIZTEGUI

El objetivo del programa es promover, coordinar y realizar actividades de investigaciones clínicas, epidemiológicas y biomédicas en enfermedades virales humanas, capacitar recursos humanos para contribuir al fortalecimiento de los servicios de salud, y producir y/o proveer biológicos específicos para el diagnóstico, tratamiento y prevención de patologías prevalentes y emergentes en el campo de las enfermedades virales humanas.

Este programa presta distintos servicios de salud (atención médica, diagnóstico de laboratorios, etc.) y mantiene una propuesta vigorosa de desarrollo asociada a sus actividades de

investigación, capacitación y producción. Estas últimas cubren áreas (Producción de animales de laboratorio, de cultivos celulares, de plasma humano para uso terapéutico en la FHA, de reactivos de diagnóstico y de vacunas virales para uso humano) no atendidas por otros sectores públicos o privados en el país y, asociados a estas actividades. Las actividades descriptas implican la necesidad de capacitar permanentemente a los recursos humanos propios, e incorporar equipamiento para mantener tecnológicamente actualizada la transferencia de conocimientos a la sociedad.

CONTROL DE CALIDAD DE BIOLOGICOS

CENTRO NACIONAL DE CONTROL DE CALIDAD DE BIOLOGICOS

El Centro Nacional de Control de Calidad de Biológicos tiene definidos programas y subprogramas de acuerdo a la responsabilidad primaria y las acciones definidas en el Anexo II del Decreto N° 1628/96.

Las responsabilidades primarias se pueden enunciar como todas las acciones, que incluyen el control de calidad de vacunas, inmunoterapéuticos y reactivos para el diagnóstico, a ser utilizados en el país para la prevención, terapéutica y diagnóstico de enfermedades toxoinfecciosas, coordinando acciones con la Administración Nacional de Medicamentos, Alimentos y Tecnología Médica (ANMAT).

Las dos unidades que integran el Centro Nacional de Control de Calidad de Biológicos (Departamento de Contralor Nacional de Biológicos, del ex Instituto Nacional de Microbiología "Dr. Carlos G. Malbrán" y el Departamento de Control de Calidad del ex Instituto Nacional de Chagas "Dr. Mario Fatała Chaben") desarrollaban las acciones descriptas, en forma separada, antes de su integración en el marco de la Administración Nacional de Laboratorios e Institutos de Salud (ANLIS).

Las acciones específicas de alcance nacional, son las siguientes:

- Control de calidad de vacunas bacterianas, vacunas virales, inmunoterapéuticos y reactivos de diagnóstico, a fin de certificar que satisfagan normas nacionales y/o internacionales de regulación.
- Elaboración de normas nacionales para la regulación y el control de calidad de los inmunobiológicos, de los procesos que les dan origen, así como de los procedimientos de diagnóstico.
- Desarrollo y adaptación de nuevas tecnologías para el control de productos y procesos de producción.
- Elaboración y mantenimiento de patrones de referencia.
- Participación en programas de vigilancia epidemiológica del Ministerio de Salud.
- Asesoramiento a los organismos públicos y privados que produzcan biológicos.
- Participación en estudios de colaboración con laboratorios del país y del exterior.

- Capacitación del personal de planta en instituciones locales y del exterior.

CONTROL DE TUBERCULOSIS Y OTRAS ENFERMEDADES RESPIRATORIAS

INSTITUTO NACIONAL DE ENFERMEDADES RESPIRATORIAS

DR. EMILIO CONI

El Instituto Nacional de Enfermedades Respiratorias "Dr. Emilio Coni" fue creado como Centro Nacional de Lucha Antituberculosa en 1961, e inició sus actividades en enero de 1962, teniendo como objetivo básico dar impulso y normatizar el control de la tuberculosis en la República Argentina.

Con el paso del tiempo se han ampliado las actividades, incluyendo el estudio de otras patologías que por su trascendencia significan un problema de salud para el país, en especial las que causan elevada morbilidad y mortalidad, como por ejemplo las relacionadas con la infancia (infecciones respiratorias agudas, enfermedades prevenibles por vacunas), otras infecciosas (influenza, leptospirosis, cólera) y patologías crónicas, como cáncer de pulmón, cáncer de cuello, etc.

CAPACITACION Y ATENCION DE FACTORES DE RIESGO GENETICO

CENTRO NACIONAL DE GENETICA MEDICA

El Centro Nacional de Genética Médica (CENAGEM) realiza estudios e investigaciones relacionadas a los factores genéticos y ambientales participantes en la etiología de las enfermedades crónicas físicas y mentales.

Presta servicios asistenciales de la especialidad, fija normas de atención, actúa como centro de referencia a nivel nacional e implementa y desarrolla técnicas de genética molecular.

Ejecuta actividades de capacitación y docencia en genética médica en pregrado, postgrado y divulgación general.

Es la única institución en el país que cuenta con programas de capacitación profesional en la especialidad, siendo la formación de recursos humanos fundamental para la creación y desarrollo de servicios de genética médica en el territorio nacional. También es el único organismo nacional que puede responder eficientemente a las alarmas epidemiológicas de patologías congénitas.

La investigación es la herramienta básica del Instituto. La predicción y prevención de las patologías genéticas, su diagnóstico, tratamiento y rehabilitación, se basan en la implementación y desarrollo de técnicas dirigidas a ampliar el espectro actual.

La capacitación y docencia, que incluye las residencias en genética médica, citogenética clínica e investigación, dictado de cursos y clases, becas y rotaciones de profesionales, y los servicios asistenciales que se cumplen por medio de la atención médica, estudios de laboratorio y asesoramiento de familias en riesgo, completan los fines primarios de la Institución.

COORDINACION Y APOYO A LA RED DE LABORATORIOS

CENTRO NACIONAL DE RED DE LABORATORIOS

El Centro Nacional de Red de Laboratorios tiene las funciones de coordinar la normatización del diagnóstico a través de las Redes de Laboratorio de Referencia Nacionales (LRN) para infecciones agudas y crónicas de origen viral, bacteriano, micótico y parasitario; contribuir en la elaboración y actualización de manuales técnicos y operativos elaborados por los LRN, brindar asistencia técnica a los Laboratorios de Referencia Jurisdiccionales (LRJ), capacitar a técnicos y profesionales mediante cursos y pasantías y asesorar a las autoridades sanitarias sobre el tipo de prestación de diagnóstico que un laboratorio puede realizar.

El Centro Nacional Red de Laboratorios realiza sus acciones respetando la estructura de los LRN y la autonomía de los LRJ, proveyéndoles información y asesoramiento y conectándolos con el Centro Nacional de Calidad de Biológicos y con los programas de control de enfermedades y de vigilancia epidemiológica.

(informal transcript of the English interpretation)

National Administration of Laboratories and Institutes of Health (ANLIS)

The primary mission of the National Administration of Laboratories and Institutes of Health (ANLIS) in Argentina is to address scientific and technical policies linked to competence in training personnel and to promote and approve and assess the projects of institutes and related centers developing and co-ordinating activities with a view to preventing morbidity and mortality as a result of infectious diseases and genetic or nutritional disease risks through projects for training and advice in co-operation with units of the Ministry of Health and all the Provincial States and national and international organizations. These projects involve:

- Developing and promoting knowledge of the biological characteristics of viruses, bacteria, fungi, and parasites as aetiological agents in pathologies in humans, their means of transmission and diagnosis;
- Prioritizing research activities, production, diagnosis and training of personnel with respect to controllable diseases in the coming decades, emerging diseases, re-emerging diseases or diseases of special importance with the work of laboratory networks to protect human health by establishing effective use of resources and ensuring biological and staff safety among workers in the community;
- Planning and organizing the production of vaccines, serums and reagents for the prevention and diagnosis of diseases as well as conducting studies, operational research and monitoring of health and sickness parameters in the community through epidemiological diagnosis,
- Promoting community involvement as joint activity with the Department of Epidemiology, as well as corrections to improve planning and programming of management and the definitions of policies and strategic priorities, human resources, decentralization of institutes and strategic management within the framework of new technical and productive capacities at the national and international levels,
- Stepping up the conditions for biosecurity in working laboratories of institutes to minimize the risks, intensifying the work of the national laboratory network, counting out activities for training and use of manuals, control of diagnoses, and the transfer or new technology.

The degree of pathology and resistance of micro-techniques requires new methodology for diagnostic techniques. The national reference laboratory works with other laboratories to ensure the diagnostic capacity to monitor communicable diseases and the emergence of new parameters or different, but related situations to changes occurring, new, preventive and control measures.

Research, Development and Services and in Human Viruses Producing Vaccines Against Argentine Hemorrhagic Fevers (FHA)

The purpose is to co-ordinate and carry out activities in clinical and biomedical research, viral human diseases training of human resources to strengthen health services and to produce or provide specific biological materials for the diagnosis, treatment and prevention of prevailing or emerging pathologies in the field of human viral diseases.

This programme provides a range of health services, medical treatment, laboratory diagnosis, etc. with a vigorous range of activities in the field of investigation, training and production. These activities involve continuing training of personnel and to ensure state of the art equipment and technology be transferred to local communities.

The National Centre for Biological Quality Control

The National centre for Biological Quality Control has programmes and sub-programmes geared to primary responsibility and activities set forth in Annex Two, Decree Number 1628/96. The primary responsibility is described as all these activities which include vaccine quality control, immunotherapeutic treatment, reagents for diagnosis to be employed in Argentina for the prevention, treatment and diagnosis of toxicological infectious diseases, co-ordinating activities with the National Administration for Drugs, Food and Medical Technology (ANMAT). Two units in the National Centre have under their control work with bacteria, the specific activities at the national level are as follows:

- Quality control of bacterial vaccines, viral vaccines and immunotherapeutic or reagent diagnosis that they meet national and international standards;
- The development of national standards to regulate and ensure quality control from immunobiological products, processes as well as diagnosis procedures;
- The development and adaptation of new technologies to monitor products and production processes, the development maintenance of reference standards;
- Participation in programmes for epidemiological surveying in the Ministry of Health;
- Advisory services to private and public bodies production biological products;
- Participation in studies jointly with laboratories in other countries and in Argentina;
- Training of staff in local institutions and those abroad.

Training and Attention to Factors related to Genetic Risk, the National Centre for Medical Genetics

The National Centre for Medical Genetics (CENAGEM) carries out studies related to environmental and genetic factors associated with the aetiology of chronic physical and mental disorders.

It provides training and teaching services in medical genetics at university, post-graduate and in the public sphere. It is the only institution in Argentina with professional training programmes in the field to train personnel for developing medical genetic services.

It is the only national body that can respond efficiently to epidemiological alarms associated with congenital pathologies. Research is the basic tool of the institute, prediction and prevention of genetic pathologies, diagnosis, treatment and rehabilitation, and implementation and development of techniques to expand the count spectrum of treatment.

Training and education including residencies in medical genetics (in situ) clinical situ genetics and research in courses in classes with fellowships and internships and assistant services carried out through with medical attention, studies in laboratories and advice to families at risk complete the primary purposes of the institution.

The National Centre of Laboratory Networks coordinates standardisation of diagnosis through the national laboratory networks in case of infectious and chronic diseases of viral, bacterial, mycotic and parasitic origin. It contributes to the development and updating of technical manuals developed by the national networks, provides technical advice to jurisdictional reference laboratories, and it provides training to technical staff and professionals through courses and provision of advice to health authorities on kinds of diagnoses or services that a laboratory can provide.

The National Centre carries out its activities whilst respecting the structure of the national reference laboratories and the autonomy of the jurisdictional laboratories providing information and advice and connecting them to the national biological quality centre and the programmes for the control of diseases and epidemiological monitoring.

Cuba

En materia de Bioseguridad, el Centro Nacional de Seguridad Biológica, desde su creación en 1996, ha desarrollado acciones para la capacitación y superación del personal vinculado a las actividades biológicas.

Esta capacitación está dirigida a elevar la competencia y el nivel científico técnico de los especialistas para enfrentar las crecientes exigencias derivadas del desarrollo biotecnológico.

Los temas fundamentales de la capacitación y entrenamiento del personal en Cuba, están enfocados en los principios básicos de la Bioseguridad, como son las prácticas y procedimientos de laboratorio, el uso de equipos de seguridad, los requisitos para el diseño y construcción de laboratorios. Igualmente se enfatiza en la evaluación de riesgo y en las cuestiones relacionadas con la Convención de Armas Biológicas y el Protocolo de Cartagena sobre la Seguridad de la Biotecnología.

Por otra parte, la legislación vigente en Cuba establece que los directores de la instalaciones y los jefes de laboratorio, están obligados a garantizar que todo el personal reciba la capacitación necesaria en materia de seguridad biológica, así como a entrenar y capacitar al personal para el trabajo en el laboratorio, incluyendo los planes de contingencia.

Las instalaciones deben desarrollar un programa de formación que contemple a todas las categorías de personal. Estos programas de formación son chequeados durante las inspecciones que se hacen a las instalaciones.

El director de la instalación es el responsable de todas las cuestiones de seguridad en la misma, incluyendo la descontaminación. Además, la legislación establece que en cada instalación debe existir un funcionario de bioseguridad encargado de ejecutar todas las acciones derivadas de la seguridad biológica, así como una comisión de bioseguridad encargada de asesorar al director en esta materia.

En resumen, las acciones de capacitación y superación ejecutadas desde 1996 hasta 2002 fueron 490, e incluyeron, entre otras, cursos nacionales e internacionales, talleres, seminarios y conferencias, con la participación de especialistas de diversas instituciones cubanas, así como de otros países.

Una experiencia novedosa en materia de capacitación en Cuba ha sido la impartición en el año 2000 de una Maestría en Bioseguridad, con dos años de duración. Actualmente esta Maestría se encuentra en su segunda edición, con una matrícula de 19 estudiantes.

Tal y como ha venido reiterando nuestra delegación en diferentes ocasiones, la implementación eficaz de la Convención de Armas Biológicas requiere tener debidamente en cuenta las disposiciones sobre asistencia y cooperación internacional establecidas en el Artículo X de la Convención.

Cuba considera que uno de los resultados concretos que debería tener este nuevo mecanismo de seguimiento de la Convención, es identificar posibles formas de asistencia y cooperación para los Estados que así lo requieran y posibilitar avances en el entrenamiento y educación de su personal en materia de bioseguridad y bioprotección.

Como un paso concreto en este sentido, la delegación cubana quisiera anunciar que nuestro país pone a la disposición de los Estados Partes interesados su modesta experiencia en esta esfera. En tal sentido, los Estados Partes interesados pueden contactarnos con vistas a posibilitar su participación en los cursos, seminarios y otros cursos de entrenamiento que organiza Cuba cada año relacionados con la bioseguridad.

Igualmente, quisiéramos anunciar la disposición de Cuba a considerar el envío de especialistas cubanos aquellos Estados que estén interesados para impartir cursos de entrenamiento o brindar otro tipo de asistencia que se necesite en materia de bioseguridad. Varios países ya se han podido beneficiar de la asistencia de expertos cubanos en esta esfera y hasta el momento los resultados de estas experiencias han sido muy favorables.

(informal transcript of the English interpretation)

My delegation will be giving a presentation on Cuba's experience with training and education in the field of pathogen security.

Since the establishment in 1996 a National Centre of Biological Safety-Biosafety has developed options for safety and co-operation and improvement of human resources linked to biological activities. This training is intended to enhance the skills and scientific knowledge of the

specialists to confront growing requirements associated with biotechnology developments. The fundamental issues linked to training of personnel in Cuba in this field include *inter alia* the basic principles of biosecurity, practices and procedures within the laboratory, safety equipment and laboratory design, as well as matters related to the Convention on Biological Weapons and the Cartagena Protocol on Biotechnology safety.

Current legislation in Cuba specifies that the administrators of the facilities as well as the heads of laboratories are required to ensure that the entire personnel receives necessary training with respect to biosecurity as well as training of personnel to work within the laboratories. In Cuba the director of such installations is responsible for all matters related to the safety within the facility. Furthermore, current legislation specifies that each facility must have a biosecurity specialist with executive functions as well as biosecurity commission responsible for providing advice to the director of the facility in this field.

Each facility in Cuba must develop its own training programme addressing all categories of the personnel and this training programme is periodically checked in the course of inspections of the facilities.

To sum up, training activities in Cuba as of 1996 until 2002 were 490 in number including national and international courses, workshops, seminars, conferences where participation from specialists from various Cuban institutions and others from abroad. As an innovative experience I might say that since 2000 there has been a Master's Degree in Biosecurity which lasts two years and currently is in its second cycle of running.

Now as Cuba has already said many times, real implementation of the Convention on Biological Weapons requires proper consideration to be given on provisions for co-operation to be given on co-operation and assistance with regard to Article X of the Convention. Cuba feels that one of the practical results which might or should derive from this Follow-Up mechanism under the Convention would be to seek to identify practical ways and means of providing assistance and co-operation which could be of benefit to States Parties in matters related to training of their personnel in matters related to safety and handling of pathogens.

As a specific contribution by our country to the attainment of this objective my delegation would like to announce Cuba's willingness to make available to all States Parties interested its modest experience in the fields of training and continuing education in safety and handling of pathogens. Consequently, all States interested may contact us if they wish for participation in courses, seminars or other forms of training organised in Cuba every year in this field.

Furthermore, we would like to announce Cuba's willingness to consider the dispatching of experts to participate in or to provide training in biosafety matters to States Parties interested. A number of States Parties to the Convention have in fact have already benefited from assistance provided by Cuban experts in this field and the results of that experience to date has proved very favourable.

Republic of Korea

In addition to many useful presentations by several delegations this afternoon, I would like to briefly introduce a survey done by National Institute of Health in Korea this year.

My delegation believes that awareness-raising and consensus-building on the part of the personnel working in laboratories and industries is sometimes more important than regulations by the government themselves, and that such awareness-raising provides the basis that regulations must be built upon.

As I have stated many times in this meeting, my country has been doing constant review of the existing mechanisms related to bio-safety and bio-security. The recent survey is one of specific measures for such a kind of review. The survey was done by the National Institute of Health under the authority of one of the ministries in the Korean government, in order to raise awareness of the personnel working in laboratories and industries on the one hand and to seek their opinions on the need for strengthened regime for bio-safety and bio-security. This survey was directed towards 563 institutions in total including 52 university laboratories, 244 medical institutions, 201 public health laboratories and 66 industry research institutions. So it was somewhat comprehensive.

The main themes of the questions in the survey were about the following:

- First, necessity of more strict registration of laboratories according to the bio-safety levels
- Second, opinions on the introduction of new additional system for the strengthening of bio-safety and bio-security measures

In this second category, the sub-questions about the following were included.

- First, the need for implementation of stricter bio-safety and bio-security guidelines
- Second, stricter procedures for authorization of BL3 and higher laboratory facilities
- Third, stricter procedures for import permission of pathogens from foreign countries
- Fourth, stricter procedures for permission of maintenance or storage of special or select agents or pathogens
- Fifth, stricter procedures for approval of experiments on special or select agents or pathogens

A little surprisingly, the answers to these questions were mostly positive. The most positive among them was in relation to need for implementation of stricter bio-safety and bio-security guidelines, and the least positive was somewhat naturally in relation to the need for the stricter procedures for approval of experiments on special or select agents or pathogens.

My government has been doing a constant review on the existing mechanisms for bio-safety and bio-security and will keep doing so in the future.

Thursday 28 August 2003

United States

Secure Transfer of Select Agents

Introduction

- Domestic and international transfers of select agents necessary for public health and microbiological research
- Wide range of facilities and carriers involved in transfers
- Select agent transfer security is a critical component of a comprehensive biosecurity program
 - Material vulnerable to theft during movement outside of controlled areas
- Bioscience facilities, select agent carriers, and states all responsible for transport security

Select Agent Transfer Process

- Internal transfers
 - Movement of select agents to and from laboratory areas within a facility
 - May involve laboratory, shipping, and receiving personnel
- External transfers
 - Movement of select agents from one facility to another facility
 - May involve commercial carriers

Transfer Security Objectives

- Mitigate risk of theft or diversion of select agents during transfer
 - Document, account for, and control select agents when moving between protected areas within a facility
 - Receive authorization and monitor external transfers between registered facilities before, during, and after external transport
 - Utilize methods to protect select agent shipments within commercial systems

U.S. Transfer Security Regulations

- Facility requirements
 - Register facility with appropriate agency
 - Receive authorization before shipment, verify receipt
- Carrier requirements
 - Personnel reliability standards
 - Access control at transport facilities
 - En-route security
 - Recurrent security training
- Export requirements
 - International shipments require export license

International Shipping Standards

- Packaging, labeling, and marking standards address biosafety concerns
 - UN Committee of Experts on the Transport of Dangerous Goods
 - World Health Organization (WHO)
 - International Air Transport Association (IATA)
 - Universal Postal Union (UPU)
- Opportunity for security collaboration

Facility Responsibilities

- Internal transfers
 - Screen personnel who have access to select agents or related information during transfer
 - Establish internal chain-of-custody documentation and procedures
 - Provide physical security for packages that require temporary storage and/or must await commercial transport
 - Protect select agent transfer-related information
- External Transfers
 - Utilize carriers that ensure timely delivery, confirmation, and package tracking capabilities
 - Notify receiver and sender before and after shipment between facilities
 - Limit amount of material moved to allow for air carriage when possible
 - Understand commercial carrier's security practices for dangerous goods
 - Employ tamper indicating methods to secondary container when necessary

Carrier Responsibilities

- External Transfers
 - Only allow reliable and trustworthy employees to handle, load or transport select agents
 - Prohibit unauthorized access to facilities, loading docks, and vehicles where select agents may be located
 - Create and adhere to en-route security plans
 - Track shipping progress of select agents

National Implementation

- Coordinate efforts with international institutions that currently provide safety guidance or are involved in commercial supply business
- Ensure adequate security of select agents during transfer
- Initiate system for agency authorization prior to external transfers

Summary

- Necessary to take steps that mitigate the threat of theft of select agents during transfer and transport
 - Bioscience facilities, carriers, and states have different responsibilities
 - Design security standards that address the threats of materials in transit, while also recognizing the legitimate scientific need to transfer select agents

United Kingdom

Security of Dangerous Goods in Transport - UK perspective

Overview

- UN Model Regulations came in force on 1 January 2003
- Covers all modes of transport
- General requirements for all dangerous goods plus detailed security plans for high consequence dangerous goods
- To minimise theft or mis-use of dangerous goods that may endanger persons or property

Aviation

- Well-established security regime that already covers cargo security
- Main gap = cargo-only aircraft
- ICAO joint DG/Avsec Panel meeting in Montreal next week
- Few anticipated problems with UK implementation

Maritime

- Important to ensure that new International Maritime Organisation ISPS Code measures are co-ordinated with UN model regulations for dangerous goods
- TRANSEC working to ensure co-ordination of security regimes - both for security of DG in ports and on board ships

Railways

- Carriage of dangerous goods already heavily regulated for safety reasons
- Inherently less vulnerable as trains can only travel on tracks!
- Trains carrying DG are also kept moving as much as possible - reduces vulnerability
- Few enhancements needed in UK to meet requirements of UN model regulations

Road Transport

- Main area of concern for UK - major vulnerabilities despite advice issued after 9/11
- UK faces policy, legislative and enforcement issues
- Need to reduce vulnerabilities quickly
- Currently developing a voluntary Code of Practice with industry in preparation for formal regulation
- Code of Practice will be in place by end of 2003

Road Transport Code of Practice will include

- Improvements in driver identification
- Register of hauliers that carry dangerous goods
- Better site security (fencing, lighting, access control etc.)

- Preparation for formal regulation

Formal Regulation – Issues

- Legislation - existing (e.g. Health & Safety) or new?
- Inspection and enforcement -
- Health & safety Executive?
- Police?
- Department for Transport?

Summary

- UN Model Regulations - implementation is a challenge
- Considerable amount of work still to do at international level
- National implementation takes time especially if new legislation is needed
- UK approach is to build on existing security regimes and to agree voluntary Codes of Practice with industry to seek early improvements

China

Statement on Biosecurity and Oversight: Transport & Transfer

Safe transport of biological agents to biosecurity is just like cutting of spreading routes to infectious diseases. The Chinese Government has made strict stipulation on domestic transport or transboundary transfer of biological agents and prescribed stringent punishment measures on violations.

1. Intra-facility transport & transfer of biological agents

Based on the Laboratory Biosafety Manual of the World Health Organization, China's national microorganism or infectious disease laboratories have formulated strict standard operational procedures to restrict the intra-facility transport & transfer of biological agents.

2. Inter-facility transport & transfer of biological agents

2.1 Domestic supply and transport of microorganisms

When applying for medical microorganisms of the second group, they couldn't be supplied without approval of the provincial health bureau. As for those of the first group, they couldn't be supplied unless both the provincial health bureau and the Ministry of Health have approved. It is forbidden to post medical microorganisms of the first group and some medical microorganisms of the second group.

When applying for the causal agents of the severe animal infectious diseases, they couldn't be supplied without approval of the Ministry of Agriculture. Only the professionals could collect the virulent strains of severe animal or zoonotic infectious diseases. The entities using these strains must adopt strict containment measures. Once the experiment is ended, the virulent

strains must be destructed under the supervision of competent personnel. The use and destruction situation should be reported to the Management Center of Veterinary Microorganisms.

When transporting or shipping genetically modified organisms (GMOs), the containers suitable for these GMOs' safety levels should be used and corresponding safety control measures should be applied to ensure the transporting safety.

2.2 Transboundary transfer, exchange and carrying of biological agents

When importing the pathogenic microorganisms that are unidentifiable in China or highly pathogenic, it must get approval of the Ministry of Health or the Ministry of Agriculture. When exchanging or providing medical microorganisms to other countries, it must get consent of the provincial health bureau and approval of the Ministry of Health. When exchanging or providing veterinary microorganisms to other countries, it must get approval of the Ministry of Agriculture.

When importing GMOs for research or experiment, the importer must apply to the competent authorities for approval. When overseas company wants to export GMOs to China, it must also apply to the competent authority for approval. If approved, the test samples of the GMOs could enter into China and then the experiment could be carried on according to the relevant regulations. Only when the experiment is ended and the result of safety evaluation proves it's safe, can the GMOs be reviewed and registered. When GMOs pass through Chinese territory, the owner must apply to the quarantine office for approval of the transit.

When animals, plants, animal or plant products, serum, vaccine, castoff of animals or plants is entering or transiting Chinese territory, the quarantine certificate issued by the exporting governmental or regional authority must be provided and these articles must receive quarantine at the entering port.

In order to prevent them from being used for biological weapons purposes, the Chinese government has established license system on dual-use biological agents covering 50 human or zoonotic pathogens and related equipment and technologies. Ministry of Commerce, separately or jointly with some relevant ministries, are responsible for examining the issuing of licenses.

2.3 Postal of biological agents

Postal of biological agents is a special form of intra-facility transport and has becoming more and more important. The Chinese government has made strict regulations on this issue.

Customer must abide by the national postal department's stipulation related to articles prohibited from postal. When post articles except letters, post office has authority to request the customer to take out the articles for examination.

Quarantine officers are responsible for picking out and applying quarantine on those postal articles needing health, animal or plant quarantine. Without quarantine office's agreement, post office could not post these articles. As for those postal articles whose destination is overseas, post office could not post them without the customs' examination and agreement.

The carrier, consignor or poster must apply to the quarantine office for quarantine when importing or exporting such special articles as microorganisms, human tissues, biological

products, blood or its products. Without the quarantine office's approval, the export or import could not proceed.

3. Violation punishment

Those people dealing with transport and causing spread of microorganisms due to violation of relevant regulations shall be sentenced imprisonment or shall receive criminal detention. Those people causing spread of contagious quarantine diseases due to violation of the border quarantine regulations should be sentenced imprisonment or shall receive detention or fine. Those officials causing loss of public property, national or people's interests due to negligence of his responsibility should be sentenced to imprisonment below 5 years or shall receive criminal detention.

Iran

During last week some issues related to export control restrictions and transfer were discussed. Today we are discussing the sub-item on transfer and transport of pathogens. My delegation has attentively listened to the views expressed. However, since these issues were discussed in the context of prohibitions, we would like to draw your attention to the following points:

1. Narrow interpretation of the Convention only in terms of Articles I and III without referring to their relation with Article X is not in conformity with the objective and purposes of the Convention. In our view, any interpretation of the Convention shall consider all provisions and Articles of the Convention which are the combination of the basic rights and obligations. This explicitly means any national implementation of the prohibitions based on Articles I and III shall also consider the consistency of any national measures with the objects and purposes of the Convention.
2. In accordance with Article X, States Parties have the right to participate in the fullest exchange of equipment, materials and related technologies for peaceful purposes.
3. Based on explicit provisions of Article X, any measures for implementation of the Convention, including national measures, shall not hamper the economic or the technological development of States Parties for peaceful purposes.

Friday 29 August 2003

United States

Registration of Facilities

Facility Registration

- Management
- Responsibilities
- Records
- Notifications

Who Must Register?

- Any agency (Federal, State, or local), academic institution, corporation, company, partnership, society, association, firm, sole proprietorship, or other legal entity
- Possesses, uses, receives, or transfers select agent or toxin in the US

Exclusions/Exemptions

- Facilities receiving specimens for diagnosis, verification, or proficiency testing
 - Upon identification of select agent/toxin, must notify authorities and transfer or destroy
- Public health emergencies
- Agricultural emergency

How Does One Register?

- Submit completed application
- Apply for Security Risk Assessment approval for access to select agents and toxins:
 - The entity (institution)
 - The Responsible Official
 - Any individual who owns or controls the entity
 - Individuals with authorized access to Select Agents and toxins

What is Included in the Registration Package?

- Names of select agents or toxins
- Location of select agent/toxin storage and work areas within each building
- Information about safety, security, emergency response, and training
- Name of Responsible Official
- Names of individuals requesting access

Certificate of Registration

- List of specific select agents or toxins
- Select agent activities; locations within buildings
- Names of individuals and select agents or toxins they have access to

- Applies to a single physical location
- Laboratory may be inspected prior to registration
- Valid for 2-3 years

Responsible Official

- Person representing the entity with authority and responsibility to ensure requirements are met
 - Safety, security, and emergency response plans
 - Allow only authorized personnel to have access
 - Provides training
 - Transfers select agents or toxins
 - Reports loss, theft, or release
 - Maintains records

Approval of Personnel

- Applicant provides personal information to the Department of Justice
- Department of Justice conducts security risk assessment by searching databases
- Assessment results returned to Secretary of Agriculture or Health and Human Services for decision
 - Access will be denied or revoked if individual is:
 - “Restricted person”
 - Access may be denied if individual is reasonably suspected of:
 - Has committed Federal crime of terrorism
 - Knowing involvement in organization engaged in terrorism
 - Being an agent of foreign power
- Approvals are valid for 5 years

Records to be Maintained

- List of approved individuals
- Inventory of select agents and toxins
 - Name, quantity of toxins (when, from where)
 - Transfers (when, to/from whom, how much)
- Entry into restricted areas (who, when entered and left)
- Inspections
- Safety, security, and emergency response plans
- Training
- Transfer documents

Maintain all records for 3 years

Notifications

- Report immediately upon discovery of theft, loss, or release of select agent or toxin
 - By phone, fax, or email to Dept. of Health and Human Services
- Written report within 7 days

China

Statement on Biosecurity: Biosecurity Oversight, Management and Enforcement

The Chinese Government has all along attached great emphasis on the oversight, management and enforcement of biosecurity. All units engaged in pathogenic microorganism experiments, such as health, scientific research, education, production units, are required to establish and improve rules for the proliferation prevention of pathogenic microorganisms, establish measures for personal protection and strictly abide by experimental operation guidelines. Samples, equipment and contaminated materials after the experiment shall be strictly decontaminated before disposal according to relevant provisions.

The General Guidelines for Microorganism and Biomedical Laboratories of China clearly establishes requirements for safety equipment, personal protection equipment and measures, special design and construction of laboratories, management rules and safety operation guidelines in the laboratories.

China's Law on the Prevention and Control of Infectious Diseases stipulates that, anyone engaged in the experiment, storage, bringing, shipment of pathogenic microorganisms violates relevant stipulations and leads to the spread of pathogenic microorganisms shall be investigated for criminal liability according to the Criminal Law or receive other punishment.

With the continual discovery of new microorganisms and the development of international antiterrorism situation, China is planning to formulate Regulations on the Administration of Medical Microorganisms, with an aim to strengthen the management of medical pathogenic microorganisms, effectively protect and make full use of China's medical microorganism resources. The said Regulations will contribute to the prevention and control of infectious diseases, prevention of pathogenic microorganisms proliferation as well as biological terrorists' use of such microorganisms.

The Netherlands

I would like to get back to the presentation of working paper 14 we held last Monday. We announced that we aimed to give a preliminary overview of observations with regard to some of the questions in our working paper, based on the discussions this week.

1. Some remarks upfront: not all questions we posed to ourselves in the working paper were addressed this week. Furthermore, some presentations and interventions during the discussion only touched upon small aspects of questions we posed, so this presentation is necessarily brief. I would nevertheless like to present the following questions and our observations to you.
2. Our first question was: *what measures, dealing with certain areas of concern as identified in our paper, would best be taken by the Government, or could be left to self regulation.* As some of the suggested measures in our paper (registration and licensing of institutions working with listed pathogenic agents and toxins, licensing of individual

personnel or licensing of transporters) self evidently suppose government involvement, this question should be answered accordingly. However, the assessment whether there is indeed a need to set up thorough licensing systems on all three issues remains to be made. At least one country explained that it indeed has a broad licensing and authorization scheme, related to the working with pathogens by facilities, or by individuals.

3. There seem to be different approaches with regard to regulating the permission to perform work with pathogenic agents and toxins by individuals: at least one country opts for giving a special authorization to individuals as referred to above, while leaving a background check to industry itself. Other countries however seem to prefer registration of individuals and a mandatory federal background check.
4. With regard to laboratory handling procedures aimed at the prevention of unauthorized acquisition of pathogens as well as physical security of laboratories and premises, we have learned that one country already has adopted very detailed guidelines, based on an obligation in federal legislation. Other countries also have enacted legal obligation for laboratories to work on security issues, in addition to obligations in the field of bio-safety. However, in these countries there seems to be more room for some kind of self-regulation. Guidelines developed by f.i. WHO, OIE or FAO on bio-safety, and possibly in the future also on bio-security, could very well assist countries or industry in developing their own national system to prevent unauthorized acquisition of pathogens.
5. With regard to measures aimed at transport of certain dangerous pathogens we noted that no country seems to have adopted a strict, governmental, licensing scheme for carriers before they are allowed to carry out this type of transport. There are however international and national certification procedures for carriers of hazardous material. One country indicated that under recent legislation security measures have been enacted with regard to transportation such as security training and security of the transport facility. Furthermore, background checks are required of anyone that has access to dangerous pathogens during transport.
6. The second question we identified in our paper was: *should there be a focus on establishing minimum standards for security measures or is detailed legislation necessary*. As mentioned earlier, one country seems to have adopted very detailed guidelines, based on input by the industry itself. Non-compliance with these guidelines would be subject to prosecution. Transfers of certain classified agents in this country will only be possible between laboratories that are registered and found to be complying with the bio-security guidelines.
7. It is not yet clear how other countries have dealt with, or are going to deal with this issue. We noted that a number of countries have directly incorporated the WHO bio-safety guidelines in legislation. These guidelines obviously contain minimal requirements, and therefore we could say that these countries seem to opt for the minimal requirements approach, leaving room for industry to elaborate on that.
8. The third question was: *which of the suggested measures should and could be taken at the international level*. It has to be said that this was not addressed with regard to all aspects on this week's agenda. With regard to the issue of transport, reference was made

to future international guidelines on security. Nevertheless we think at this moment that some harmonisation of security measures might be beneficial for all countries.

9. The fourth and fifth questions were: *Is the best solution to adopt one law/regulation covering bio-security or should this be added to existing laws and regulations? and is it best to create one oversight body specifically dedicated to bio-security, or should this be added to existing agencies and inspectorates?* These questions were dealt with to some extent. It appears that some countries have enacted new legislation, (primarily with a general focus on the prevention of terrorist activities) that also includes a reference to enhancing the security of dangerous pathogens in order to prevent possible misuse. Most countries seem to have tasked existing oversight agencies, such as Health or Agriculture inspectorates with the oversight of compliance with security measures. Others have also involved the police in routinely checking security measures at certain identified facilities. Governmental Security or Justice Departments are usually involved with background checks. We did not hear any country adding security aspects to either the direct implementing legislation, or complimentary legislation dealing with import and export, or bio-safety measures. We did not hear a country set up a completely new oversight body for security measures from scratch.
10. The last question was: *How to balance security with scientific progress and transparency and with administrative burdens?* We noted that this aspect repeatedly came back with regard to most measures. The question forms an integral part of the evaluation of an individual risk, or vulnerability assessment. On a wider scale, references were made to exceptions for the transfer of diagnostic samples, and with regard to the benefit of human health as a whole. Some references were also made to peer review, complementary to, or instead of rigid government enforcement. It was furthermore suggested that countries that have a less or no sophisticated biotech industry might not have to adopt the same security measures as countries with a very large and sophisticated industry.

Cuba

En Cuba el proceso de autorizaciones se encuentra legislado en la Resolución 76 de 2000. De acuerdo a esta resolución, las autorizaciones de seguridad biológica se clasifican en:

1. Licencia de Seguridad Biológica: Autorización que ampara las actividades que presentan un elevado nivel de riesgo biológico para el trabajador, la comunidad y el medio ambiente.
2. Permiso de Seguridad Biológica: Autorización que ampara las actividades que presentan moderados niveles de riesgo biológico para el trabajador, la comunidad y el medio ambiente.
3. Notificación: Autorización que ampara aquellas actividades que apenas presenten riesgo, debido a lo ínfimo de sus niveles

La previa obtención de la autorización de seguridad biológica, es requisito indispensable para la realización de las actividades siguientes:

- a). el emplazamiento, diseño, proyecto, construcción, remodelación, puesta en servicio, explotación y proceso de cierre de las instalaciones donde se hace uso de agentes biológicos y sus productos, organismos y fragmentos de éstos con información genética,
- b). la investigación, producción y ensayos sobre el terreno que involucren agentes biológicos y sus productos, organismos y fragmentos de éstos con información genética,
- c). la liberación al medio ambiente de agentes biológicos y sus productos, organismos y fragmentos de éstos con información genética ,
- d). la importación y exportación de agentes biológicos y sus productos, organismos y fragmentos de éstos con información genética,
- e). la transportación de desechos biológicos peligrosos y
- f). otras relacionadas con el cumplimiento de los compromisos contraídos por la República de Cuba en instrumentos jurídicos internacionales.

En relación a este último inciso, el Reglamento para la Contabilidad y Control de materiales biológicos, equipos y tecnologías aplicados a estos, en fase de aprobación, establece que es necesario solicitar un Dictamen de Salvaguardia para la realización de las actividades siguientes:

- a) La recepción o envío, transferencia de agentes biológicos y tóxicos, y organismos pertenecientes a los grupos de riesgo que se determine, así como de equipos, tecnologías y materiales en general, entre instalaciones nacionales que los utilicen o entre Cuba y otros Estados, con el fin de asegurar que no sean utilizados para llevar a cabo actividades prohibidas nacional o internacionalmente.
- b) Los procedimientos para la destrucción o inutilización de agentes biológicos y tóxicos, cuando por su volumen, características y ubicación se consideren peligrosos o puedan ser violatorios de tratados internacionales de los que Cuba sea parte.
- c) El uso previsto para los materiales biológicos, equipos y tecnología.
- d) Otras actividades relacionadas con el cumplimiento de compromisos contraídos por la República de Cuba en instrumentos jurídicos internacionales sobre la materia o relacionados con ella.

Con el objetivo de verificar el cumplimiento de la legislación cubana en materia de seguridad biológica y perfeccionar el desarrollo de esta disciplina, el Centro Nacional de Seguridad Biológica ha desarrollado un Sistema de Inspecciones.

Este proceso de inspección nos permite valorar la implementación de las regulaciones establecidas de forma particular y profunda en cada una de las instalaciones incluidas en el sistema nacional de seguridad biológica. Los resultados de las actividades de inspección proporcionan información actualizada sobre el estado de la seguridad biológica en los organismos y entidades que son objeto de control, permitiendo establecer directrices de trabajo eficaces para el mejoramiento del sistema nacional.

El sistema de inspecciones es aplicable a todas las instalaciones con riesgo biológico del territorio nacional, así como a las áreas de liberación de organismos al medio ambiente. Asimismo, serán objeto de inspección todas aquellas entidades y organismos responsables de actividades de importación y exportación de agentes biológicos u otros organismos.

Esta actividad se desarrolla de forma sistemática con la participación de los inspectores del Centro Nacional de Seguridad Biológica, especialistas que atienden esta disciplina en las delegaciones territoriales del Ministerio de Ciencia, Tecnología y Medio Ambiente y expertos técnicos que se han identificado y que hayan recibido la capacitación requerida, que incluye conocimientos de seguridad biológica y de la actividad de inspección.

Para la preparación de los inspectores se ha diseñado cursos de actualización y acreditación de los inspectores. El próximo de estos cursos se desarrollará en el presente mes de septiembre de 2003.

Para el caso de específico del cumplimiento de las obligaciones contraídas por Cuba como Estado Parte en la Convención de Armas Biológicas, el Reglamento de Contabilidad y Control, el cual se encuentra en fase de aprobación, recoge los siguientes aspectos:

La Autoridad Nacional, por intermedio de sus inspectores, efectuará inspecciones a las instalaciones, a los efectos de verificar la ejecución y control de lo dispuesto en el Reglamento de Contabilidad y Control.

Los inspectores de la Autoridad Nacional tienen acceso a todas las áreas de la instalación donde se hace uso de materiales biológicos, equipos y tecnología aplicada a éstos, así como a todos sus registros. Estas inspecciones pueden ser realizadas también durante la ejecución de la construcción de las instalaciones.

Las inspecciones tienen como objetivo verificar:

- a) La veracidad de las informaciones enviadas por la instalación y por los Organismos Centrales del Estado, involucrados en el proceso de intercambio de información, así como, su actualización y correspondencia con el registro de operación y los informes enviados.
- b) La no realización de las actividades prohibidas por la Convención de Armas Biológicas.
- c) El cumplimiento de las exigencias orientadas por la Autoridad Nacional.
- d) La elaboración y la actualización de los registros de operación.
- e) El cese de la contabilidad y el control.

Las inspecciones ordinarias de Salvaguardia se realizan, como mínimo, cada dos años, por el Centro Nacional de Seguridad Biológica.

Las inspecciones se notifican con un tiempo de antelación de cuarenta y ocho (48) horas como mínimo a la dirección de la instalación.

No obstante se pueden realizar inspecciones especiales sorpresivas, cuando la Autoridad Nacional o el Centro Nacional de Seguridad Biológica así lo consideren, no requiriendo notificación previa.

Si los inspectores detectan usos no autorizados, o contrarios a los objetivos establecidos en la Convención, o cualquier violación en el sistema de contabilidad y control, se procede conforme al procedimiento establecido en materia de infracciones administrativas.

Resumiendo, desde 1996 hasta el 2002 se han emitido 249 autorizaciones y se han denegado 7. Desde 1998 hasta el 2002, se ha realizado un total de 2945 actividades de inspección.

Tanto el sistema de autorizaciones como el de inspecciones, nos han permitido valorar la implementación de las regulaciones establecidas de forma particular y profunda en cada una de las instalaciones incluidas en el sistema nacional de seguridad biológica.

(informal transcript of the English interpretation)

I wish to make a brief presentation about the systems currently being used in the Cuban Republic. In Cuba, the process for authorization has gone up to the year 2000 in accordance with these regulations the biosafety regulators specify the need for biosafety which is based on activities with a high degree of risk. The permit for biosafety which covers the activities with moderate risks, as also notification for those activities with a very small risk. Prior obtaining of biosafety accreditation is indispensable for carrying out the following activities:

- The placement, design, project for, building of, remodeling, and servicing of the facilities where use will be made of biological agents and their products, organisms.
- The research, production and testing carried out in the field which involves biological agents and their products.
- Importing and exporting of biological agents and their products.
- The assessment of dangerous products and other activities related to complying with the commitments entered into by the Republic of Cuba pursuant to international legal instruments.

With reference to this latter point, the regulation for accountability and control which is currently being adopted sets forth what is necessary to request a safeguards decree for the following activities:

- Pursuant to the request concerning biological agents and toxins and bodies belonging to groups the risk of which has been determined previously and also technological equipment and materials in general entering Cuba or other states in order to ensure that they are not used to carry out activities which are prohibited national or internationally
- The procedures for the destruction and/or dismantling these agents where, because of their volume, characteristics or location, they're considered to be dangerous or may violate international treaties to which Cuba is a party;
- The use of bacteriological agents and technology and equipment and others related with the fulfillment of commitments entered into by the Republic of Cuba.

The system for authorization established enables us to establish the level of biological risk pursuant to the national system for security according to the rules established.

Mexico

México continúa convencido de que mediante las negociaciones multilaterales emprendidas en el marco de esta Convención se preservará y fortalecerá la prohibición de este tipo de armas de destrucción en masa. Sin embargo, mi delegación no puede ocultar su frustración por los límites que hemos impuesto a nuestro mecanismo de examen.

Si bien el gobierno mexicano mantiene su interés en favor de la adopción de medidas de verificación que aseguren la plena observancia de la Convención, no descarta la posibilidad de lograr avances en otras tareas también encaminadas a evitar los riesgos del uso de los agentes biológicos y tóxicos con fines diferentes a los pacíficos.

México manifiesta su interés en lograr progresos en la búsqueda de consensos en las diferentes vías encaminadas al cumplimiento cabal de la Convención sobre la Prohibición de las Armas Biológicas, y reitera su compromiso de informar respecto de las acciones realizadas por México en aras de la completa observancia de las disposiciones contenidas en este instrumento jurídico internacional.

México destaca su plena disposición para lograr avances y entendimientos en los diversos rubros a examinar y promover por los Estados Partes de la Convención para la Prohibición de las Armas Biológicas en el marco de las reuniones anuales y en las reuniones de expertos en este tema. Sin embargo, reitera su interés en concluir la tarea pendiente de dotar a ese instrumento jurídico internacional con un mecanismo de verificación que garantice su cabal cumplimiento.

Observamos con interés las medidas adicionales propuestas por algunos Estados Partes dirigidas al fortalecimiento de las legislaciones nacionales, al establecimiento de estándares de seguridad en el manejo y transporte de microorganismos patógenos y a los sistemas de control nacional de actividades de ingeniería genética y biotecnología.

Asimismo, apreciamos los méritos de las propuestas que buscan al establecer mecanismos eficaces de cooperación internacional para investigar brotes sospechosos de enfermedades y diseñar procedimientos para resolver preocupaciones derivadas del cumplimiento de la Convención, así como para la capacitar al personal para trabajar en equipos internacionales de respuesta rápida ante posibles emergencias biológicas, entre otras iniciativas.

Sin embargo, México considera que los avances en los aspectos de la legislación nacional de los Estados Partes para la aplicación de la Convención, así como los desarrollos de cooperación internacional en este campo no sustituyen la necesidad de dotar de medidas de verificación a la Convención, que permitan demostrar el cumplimiento de sus disposiciones.

Finalmente, mi delegación quisiera llamar la atención de esta reunión que ha presentado un documento de trabajo en el cual se reflejan algunas de las medidas relativas a la aplicación de la Convención tomadas por mi país.

(informal transcript of the English interpretation)

Before concluding our session, my delegation would like to share with you some general considerations. Mexico continues to be convinced that through multilateral negotiations, which we have undertaken within the framework of our Convention we shall preserve and strengthen the prohibition on this type of weapons of mass destruction. However, my delegation cannot hide its frustration at the limitations we have imposed on our mechanism for consideration. While the government of Mexico continues to be interested in the adoption of measures of verification ensuring the full observance of the Convention, it does not set aside the possibility of achieving something in other areas which is also intended to avoid the risks of the use of biological weapons and toxins agents with purposes other than peaceful ones.

Mexico expresses its interest in achieving progress in consensus-seeking through various paths in order to achieve faithful compliance with the Convention and reiterates its commitment to provide information concerning activities carried out by Mexico, with a view to achieving the full observance of the provisions contained in this international legal instrument. Mexico stresses its full readiness to achieve progress and understanding in the various headings under examination and to promote with the States Parties of the Convention, within the framework of annual meetings, as also within the framework of expert meetings, progress in this area. But, it repeats its interest in concluding the task that remain outstanding, that is to adopt this international legal instrument with a verification mechanism that will ensure faithful compliance.

We note with interest the additional measures being proposed by some States Parties intended to strengthen national legislations and to establish safety standards for the transport of pathogenic microorganisms as also for national control activities and genetic engineering and biotechnology. Similarly, we appreciate the merits of these proposals which seek to establish effective international cooperation mechanisms in order to investigate suspicious outbreaks of diseases and to design procedures in order to deal with any concerns relating to compliance with the Convention and also to train personnel to work in international rapid response teams in the face of biological emergencies amongst other initiatives.

However, Mexico does consider that advances in aspects of national legislation of the States Parties for the implementation of the Convention as also the development of international cooperation in this field does not replace the need to adopt verification measures for the Convention enabling us to prove that there has been full compliance with its provisions.

Finally, my delegation would like to draw the attention of this meeting to the fact that a working document was submitted reflecting some of the measures concerning the application of the Convention as taken by Mexico.

Iran

Final Statement

Before the conclusion of the Meeting of Experts, I would like to inform of the following overall view and conclusion of the whole process:

The Islamic Republic of Iran considers the multilateral approach as the most effective measure to strengthen the treaties on weapons of mass destruction, the Biological Weapons Convention in particular. Although the expert meeting on national measures for the implementation of the regulatory pillar of the Convention is beneficial, the approach has to be comprehensive covering all provisions of the Convention, especially the promotional ones. One cannot come to feasible and applicable conclusions at this stage where the mandate on the issues related to international cooperation is still pending and is to be fulfilled during the course of deliberation next year. Therefore there is high expectation especially from industrial countries to contribute fully to our common cause in promotional aspects of the Convention as well.

Republic of Korea

In general, my delegation is satisfied with our lively exchange of views and discussions. In this regard, I am convinced that this meeting, which has been qualitatively different from the previous review conference, has laid a good foundation for the next meeting of the States Parties and the Sixth Review Conference.

My delegation is of the view that information sharing on national implementation measures and the exchange of best practices and lessons learned on the timely and pertinent subjects addressed have served our objectives in two important ways:

Firstly, States Parties have renewed their commitment that their first and foremost obligation should be to take the necessary steps to translate the prohibitions of the Convention into action through all legislative, administrative and regulatory means. The lack of a verification protocol shouldn't serve as a justification for a State Party to fail to equip itself with real teeth at the national level. Another asset we can each bring back to our capitals is the recognition of the differences in national implementation measures as well as some concrete ideas on how to improve the existing systems. We would like to reiterate our position once again that effective domestic measures should include stringent national export control systems as well as penal measures against any activities in contravention of the Convention.

Secondly, we have affirmed that in order for the instrument to be a viable and resilient mechanism, we must continue to assess the developments affecting their objectives and operations. Indeed, multilateral arms control and non-proliferation agreements should not remain static, but should instead grow stronger and more efficient in fighting against new and emerging threats. In this regard, my delegation reaffirms that our second topic – national mechanisms to establish and maintain the security and oversight of pathogenic microorganisms and toxins – is of utmost importance at this juncture. The presentations and discussions on this issue have indeed increased our awareness on safety and security needs in the face of the ever-increasing threat posed by biological weapons. I am confident that the national presentations and ideas discussed thereon will serve as useful food-for-thought in improving our respective systems, thereby minimizing the risk of accidental release of pathogens as well as preventing unauthorized transfer, theft and diversions thereof. I would like to take this opportunity to thank those delegations who have made their national experts available to assist those in need in this field.

My delegation also wishes to call upon all States Parties to keep reviewing the efficacy and effectiveness of their respective domestic systems in implementing the Convention and take

additional measures as appropriate. In addition, as you rightly suggested, my delegation hopes that the Meeting of States Parties in November will give focused consideration to a few core questions identified at this Meeting.

Chairman

As we wrap up our work, that is the first Meeting of Experts, it is clear to me that this forum has provided an opportunity for States Parties to exchange a wealth of information on those topics under consideration. As this was an entirely new process, this Meeting of Experts has been a learning experience and a challenge for all of us. I believe that the result of our two weeks work in this new format has laid a foundation for future work in November and beyond. As it is captured in the procedural report, this meeting heard 67 thematic presentations, and 40 national overview statements from delegations, in addition to the 66 working papers which were prepared.

I think one of the most valuable elements to emerge from the first week of discussion was the identification of certain recurring elements of effective national implementation approaches. Several States Parties expressed their views on what these recurring elements are including, but not limited to the need for legislation which encompasses the full scope of the provisions in the Convention; effective penal provisions to punish and deter violators; and effective regulations or legislation to control and monitor transfer of technologies. The sharing of expertise on these topics will undoubtedly be beneficial to the further implementation of the Convention.

As for the second week, you have heard my points about the core issues, recurring elements, and I would just like to make one point: that I'm sure that the high quality and the comprehensiveness of the information that was presented during the second week as well, has given many States Parties an insight into what effective security and oversight of pathogenic organisms and toxins requires and also the practical ways in which this can be achieved. Obviously there is a wide range of technical capacity on these issues in various States Parties and I am very heartened by the offers we heard today as well, during this week, and during the previous week about availability of national expertise and experience to be shared with others.

With regard to the output of this meeting, as we have discussed, the entire collection of daily collations, not including the daily summary, will be included as an annex to the procedural report. I believe that this annex can serve as a very valuable type of document for all States Parties both in preparation for the November meeting and far beyond. In addition, as it is clear from the report as adopted in an informal setting, it is my intention to distribute to all delegations today an updated edition of the CD-ROM information repository, with the understanding that some of the more recent contributions will have to be reflected in an updated version. In addition to the documentation contained electronically in the CD-ROM, the inventory of national measures of several States Parties has been updated. At the same time, due to the short timeframe, we were not able to update all States Parties' legislation based on the documents we received during this meeting. But this information as well will be incorporated in the next version of the CD-ROM which I intend to release in advance of the November meeting.

I hope that delegations will take the vast amount of information provided during this meeting home with them and use it as a valuable resource in their national efforts to further implement the prohibitions in the Convention and to improve the security and oversight arrangements.

Although the discussion of these issues is limited to 2003, States Parties can and must continue their efforts at the national level to address issues raised during this meeting.

Looking towards November, I hope that when you return to your capitals, you will review the information shared this week in presentations, statements and interventions with the aim of identifying priority issues for discussion. Our time will be very limited at the Meeting of States Parties in November and I think it is essential that we focus on a few key issues if we are to achieve substantive results in November. To this end, and to structure the discussion in November, as a preliminary suggestion, I propose that States Parties do not repeat those very useful and informative statements and presentations which have been made here during these two weeks, but that we move on to more focused consideration of how to bridge the gap between the needs and requirements identified and between the enhanced national implementation and the potential national expertise sharing. I anticipate that there will be a number of regional group and bilateral meetings, during the intercessional period. I hope that these meetings will provide an opportunity for a discussion of the structure of our work in November and the desired outcomes. I would ask that any ideas along these lines also be submitted to me, if those ideas are handed over in writing that would be even better, to assist my preparations for that meeting.

In addition, I hope that ongoing discussions emerging from this meeting will promote closer consideration of the needs and core requirements which exist in various States Parties and the assistance which is available to meet those requirements. The sharing of best practices which occurred at the meeting was in my judgement useful. However, we have clearly seen throughout this meeting that there are differences in the levels of national implementation of prohibitions and of progress towards ensuring security and oversight. Those differences, to a certain degree are natural, however if implementation can be enhanced it can be an important outcome element of our meeting.

There is a need for a frank and open discussion of the situation and of the challenges facing various States Parties. Until we identify the problems, we cannot identify the solutions, so I am looking forward in that respect to a candid and frank exchange of ideas about the difficulties and the challenges being faced, in addition to the best practices discussion which was so strongly and dynamically coming through during the last two weeks.

In this context, as we heard, certain States Parties have already voiced their willingness to share their experience and expertise to build bilaterally or regionally upon the information shared during this meeting. And we heard that already some delegations compiled a list of national experts in this area that those States Parties in need of assistance could draw upon. Others are ready to undertake such a listing in the light of our further steps in preparation for November and in the November meeting. So, I anticipate other such suggestions and other offers of assistance which would be made available, be it prior to the November meeting or in the November meeting.

So, I wanted to make these remarks not as concluding remarks but just to initiate an informal discussion. If delegations already have some ideas I think it would be most appropriate to share with others. Of course this should be only a first step, so still we haven't finished our work here. Delegations of course may need more time in capitals to go through the vast amount of material – around 400 pages of statements and presentations, and the 66 working papers I referred to.

Chairman

I would like to make some remarks to this meeting.

What we began two weeks ago was something of a voyage into the unknown. We began a new process that had had a difficult birth among some of the most bitter divisions the States Parties have known in the history of the Biological Weapons Convention. Many States Parties agreed only with reluctance to this new process. Others worried that the deep political divisions over the future of efforts to strengthen the Convention would cause our new process to be ineffective, or even counter-productive.

Like many of you, I began this year with some doubts about how this new process would work. For those of us used to negotiation and codification, this new approach was to some extent an unknown quantity. I made clear to delegations in the course of my consultations throughout the first half of this year that the success or failure of the process depended on all of us and on what States Parties were prepared to contribute. There was a genuine risk that the process would just become an empty exercise, devoid of substance, filling in time until the next Review Conference.

So I am pleased to say that, despite the doubts, this Meeting of Experts has been a success. I think it is a mark of the deep conviction of all States Parties of the importance of the Convention that we have been able put aside our political differences for the moment, to focus on practical actions that will genuinely strengthen the barriers against the development, acquisition or use of biological weapons. I think also that it is a reflection of the inherent strength and flexibility of the multilateral system that it can respond to difficult circumstances and serious political differences, and still produce useful results. I sincerely hope that all delegations will take note of this: we have not spent two weeks throwing recriminations or re-hashing long-standing feuds. Our differences undoubtedly remain, but I think that all delegations will agree that the atmosphere and the nature of our discussion has been overwhelmingly collegial and cooperative. This in itself is a considerable achievement.

But the main achievement has been the substantive and thorough exchange we have enjoyed, and the vast amount of useful, practical information that has been shared. The commitment States Parties have shown to this process has been beyond expectations. Delegations of 83 States Parties participated in this Meeting of Experts and this is an outstanding number for a technical meeting of this kind. Over 400 individual delegates participated – more than at the Review Conference itself– including over 100 legal and scientific experts. Sending experts from capitals is an expensive exercise, and I applaud States Parties for making this significant investment in the future of the Convention.

This wide array of highly-qualified participants has engaged in a technical exchange of immense proportions. We have heard over 90 presentations during these two weeks, from a wide range of delegations. I hope you have all brought large suitcases, because the collations of presentations, statements and contributions run to several hundred pages. But far more important than the quantity is the quality. Here, I can say, based on the individual feedback I have received, that a great deal of useful, practical and directly applicable information will be taken back to capitals and used directly in strengthening national implementation, both on the legislative side and on the security and oversight side.

I want to emphasise again here the practical value of the work we have done. The measures we have discussed are measures that deal with real problems. We have discussed measures that would help prevent real-life incidents such as the anthrax letters in the United States in 2001, and the Aum Shinryikyo attacks in Japan, and that are immediately applicable to the continuing struggle against terrorism around the world. We are most definitely not just filling in time, but I am sure that as a direct result of this Meeting – even before we get to the November meeting – a number of measures will be undertaken to start the further strengthening of national implementation based on information shared at this meeting.

It is also clear that this meeting has stimulated some new thinking among States Parties. The concept of biosecurity, for example, as an overlapping but distinct concept to biosafety, has been widely discussed, and I think that many delegations will be encouraging their governments to further review policy in this new and developing field. Another example is the concept of complementary legislation, the role of which in strengthening the national legislative "net" covering biological weapons has been elucidated and clarified in the course of the Meeting.

Furthermore, this Meeting has stimulated important activities beyond the immediate family of States Parties. During this Meeting, we have been privileged to have had the opportunity of attending a range of presentations and seminars given in the lunchtimes and early mornings, by several intergovernmental organizations. It is clear that many of the activities of these organizations are not only relevant to and supportive of States Parties' own national implementation efforts, but are increasingly significant in their own right as part of the global effort to prevent the development, acquisition and use of biological weapons. I hope that States Parties will continue to work closely with, and to further encourage the efforts of, these organizations.

The Meeting has also triggered the development of the Information Repository which has I think been universally welcomed as a useful tool for States Parties. This Information Repository, which now contains nearly one thousand items of legislation and other measures from around 80 States Parties, has become a fundamental reference tool which I'm sure delegations will find useful both in preparing for November, and indeed beyond as they continue their own national implementation efforts in the future.

Among the wealth of information this Meeting has heard, there are a number of core themes that have emerged. Delegations from East and West, North and South, have reiterated many of the same elements as being central requirements for effective national implementation of the prohibitions in the Convention and for effective security and oversight of pathogenic microorganisms and toxins. It is not my intention to attempt to enumerate these common themes now. Instead, I will be doing what I hope you will all be doing over the coming weeks, and reviewing carefully all the information provided during this Meeting in order to distil and focus on these key elements for the Meeting of States Parties in November.

Another important element to emerge has been the various offers of assistance from States Parties, to help other States Parties, bilaterally or regionally, with their national implementation. These offers have come not just from the big developed states, but from smaller states too, from different regions. I think this illustrates very well the collective responsibility that States Parties feel for their Convention. I hope that we can further explore this important field in November, and I invite all States Parties to consider what they may be able to offer.

The November meeting will provide us with an opportunity to build on the positive start we have made here, and to perhaps look at how we might focus more directly on some key areas of implementation. As I have mentioned, we can also look at further offers of assistance. I would like to describe this mix as one of "demand and supply": we can look at what is required to further improve national implementation, and at what States Parties are willing to supply nationally to help this happen.

But I don't want to go too much into detail now on what will happen in November. As was the case for this Meeting of Experts, the Meeting of States Parties will be whatever you, the States Parties, want to make it. I will be consulting widely over coming weeks, and I invite all delegations with ideas to contact me to discuss them. One thing I would like to say is that it is my sincere hope that the collegial, constructive and practical approach we have seen at this Meeting will continue, and that delegations will approach their preparations with a confident, rather than suspicious, outlook.

I would like to thank you all for your contributions, for the extensive preparations that have gone into them, which is an achievement in itself, and for your faith and forbearance in giving this new process the best possible start, despite the misgivings which I know some of you hold. We have made a good start: so let's continue in the same vein.
