United States Department of
Health & Human Services
Office of the Assistant Secretary for Preparedness and Response (ASPR)

Considerations of Biosafety and Biosecurity under the BWC Confidence Building Measures, WHO International Health Regulations, and the UN Security Council Resolution 1540

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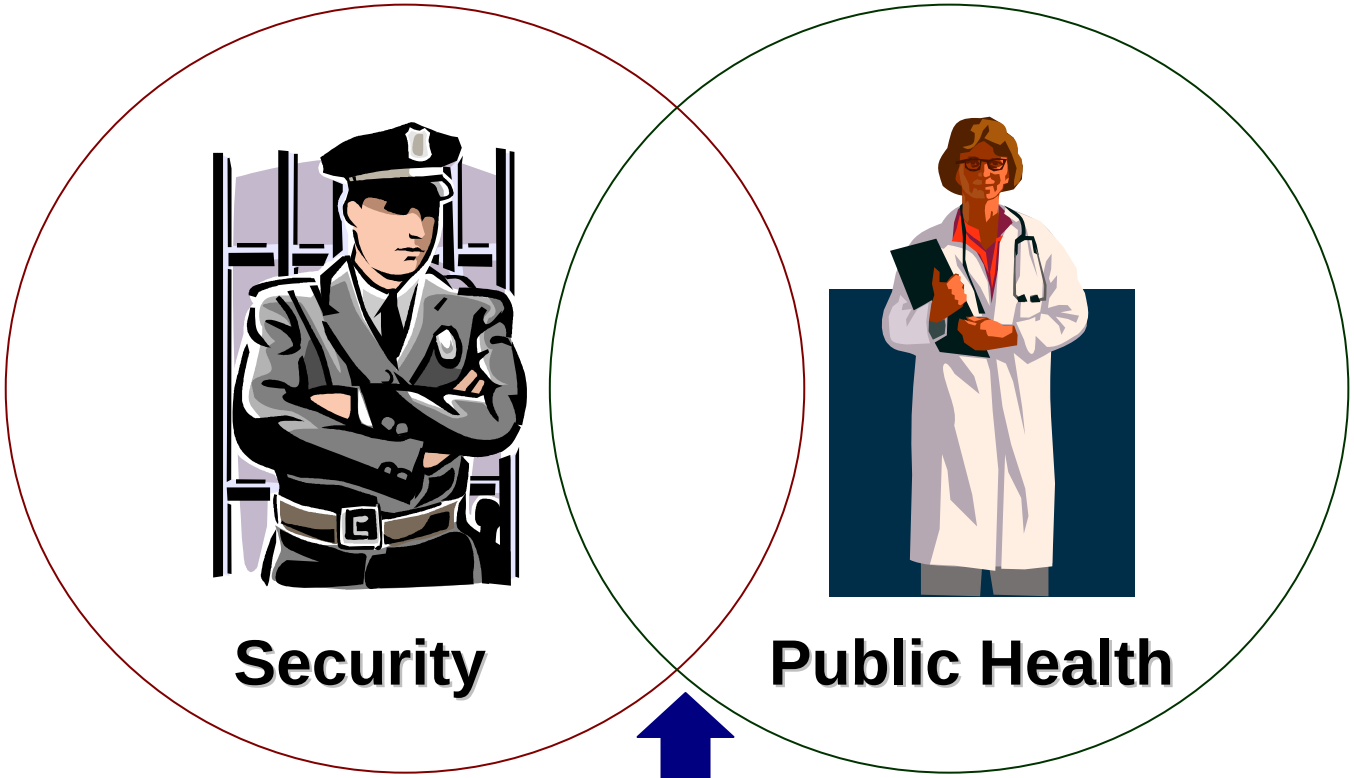
Disclaimer

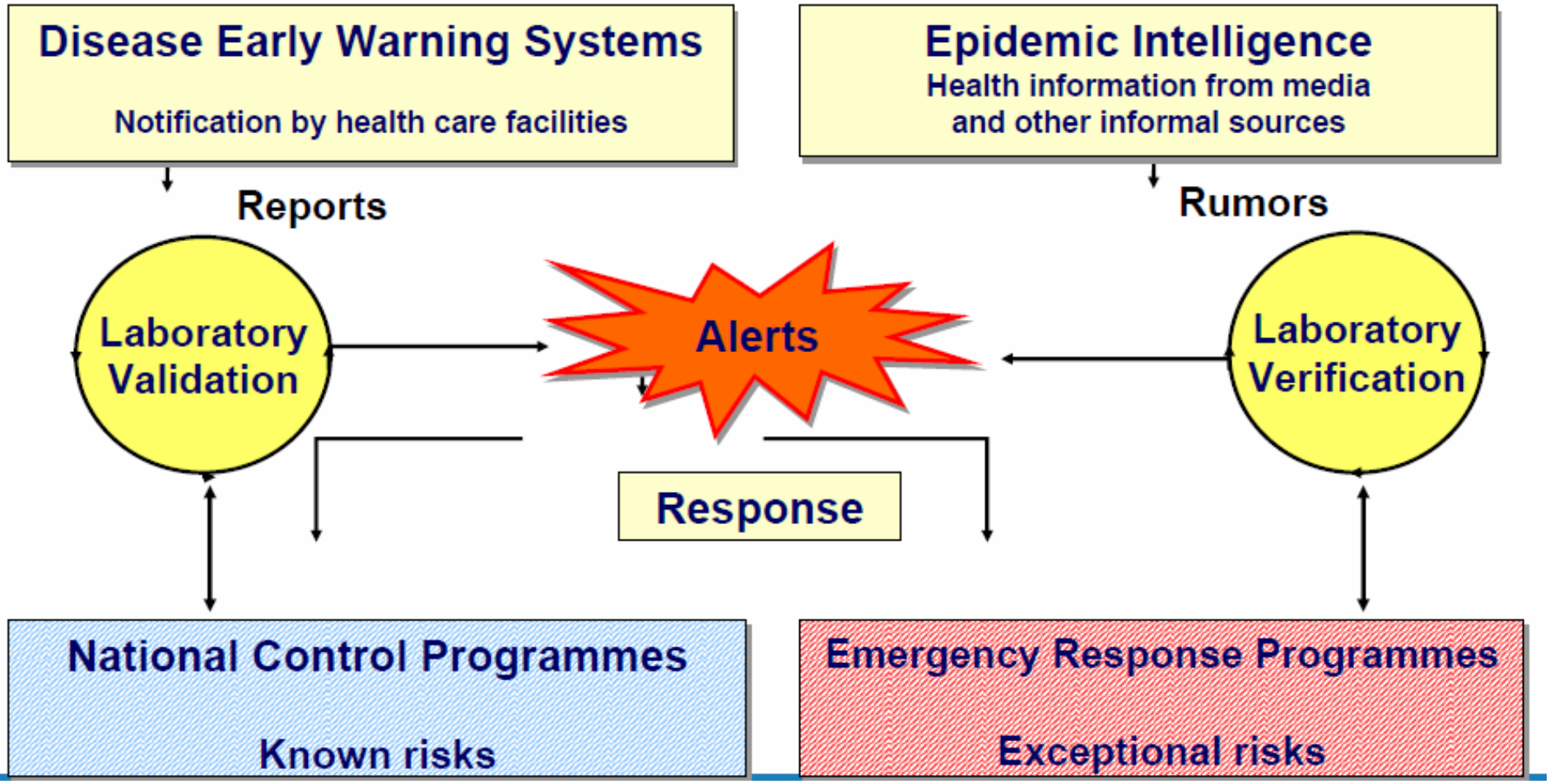
The views, opinions, findings, and conclusions expressed in this presentation are those of the author and do not necessarily represent the views, official policy or position of the U.S. Department of Health and Human Services (HHS) or its components, or the U.S. Government.



Health Security

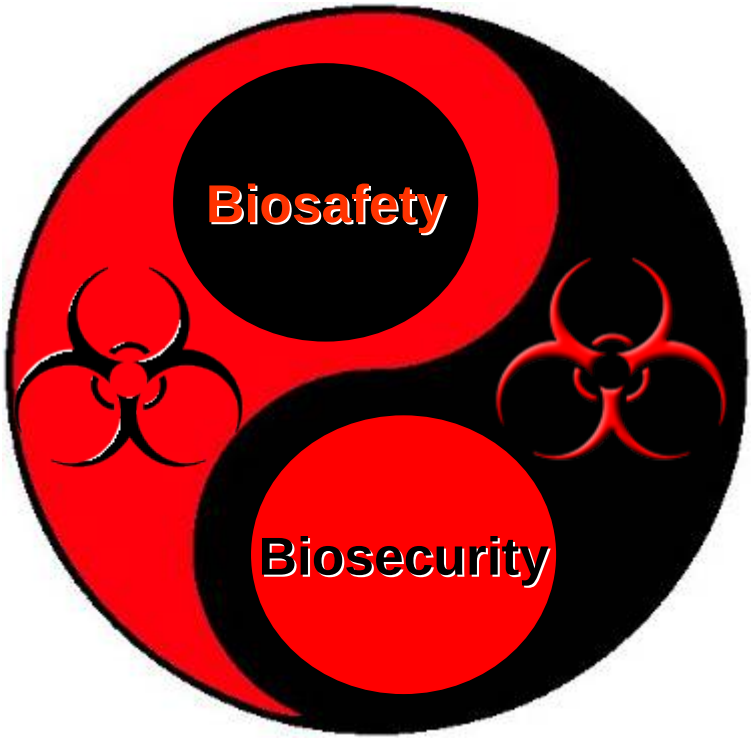
Global inter-sectoral partnership & collaboration to prevent public health risks which can pose a potential security threat

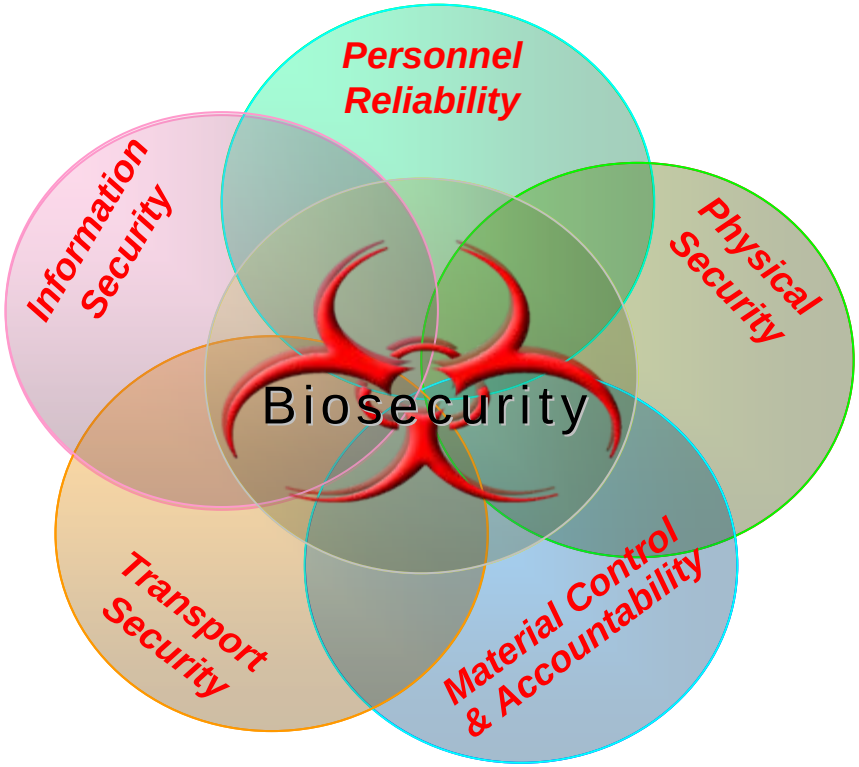
Lab Capacities & Health Security



Reference: International Health Regulations Awareness Workshop for BTWC Delegations, Geneva, 21 Aug 2009

Unified Conceptual Framework of Biological Risk Management





<u>Biosafety:</u> reduce or eliminate exposure of individuals and the environment to potentially hazardous biological agents

<u>Biosecurity:</u> prevent loss, theft or misuse of microorganisms, biological materials, and research-related information

Biological Risk Management in the U.S. is the objective of a broad but related range of strategies, legislative, regulatory and policy implementation measures that are designed to minimize the <u>(inside and outside the laboratory)</u> risk that biological materials and technologies may cause harm (either <u>accidentally or intentionally</u>), not least those measures that relate to the national implementation of WHO IHRs, UNSCR 1540, and BWC

Biosafety / Biosecurity = Cross-Cutting, Vital Elements of Health Security & Biological Non-Proliferation

	WHO IHRs (2005)	BWC	UNSCR 1540
Applicability:	**All 193 WHO States Parties**	**164 BWC States Parties**	**All 193 UN Member States**
Purpose:	**"to prevent, protect, protect against, control and provide a public health response to the international spread of disease…"**	**To prohibit the development, production, acquisition, transfer, stockpiling and use of biological and toxin weapons**	To **prohibit non-State actors** from developing, acquiring, manufacturing, possessing, transporting, transferring or using nuclear, chemical or biological weapons and their delivery systems
Requirements:	Capacities *"to detect, assess, notify, and report events"* & *"respond promptly & effectively to public health risks & PHEICs"* [Lab core capacity includes biosafety / biosecurity]	***Any necessary measures to prohibit and prevent the development, production, stockpiling, acquisition, retention, transfer or use of biological weapons***	Domestic controls to prevent the proliferation of nuclear, chemical and biological weapons, their means of delivery, and related materials
Entry into force:	**15 June 2007**	**26 March 1975**	**28 April 2004**
Mandated reporting / where / when:	Status of implementation / WHO / *"As soon as possible but no later than five years from entry into force …"; annual reporting on indicators*	***None**** **** CBM voluntary reporting / BWC ISU / every year by 15 April***	Status of implementation / 1540 Committee / *"without delay"*

What do the IHRs call for?

- **Strengthened national capacity** for surveillance and control, including in travel and transport
- **Prevention, alert and response** to international public health emergencies
- **Global partnership** and international collaboration
- **Rights, obligations & procedures,** and progress monitoring

new OBLIGATIONS OPPORTUNITIES

- If your country is a Member State of the World Health Organization (WHO), it is almost certainly a State Party to the International Health Regulations, revised in 2005.

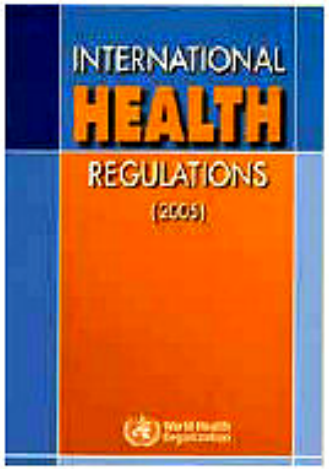
- Each State Party to the IHR(2005) therefore contributes to a global legal framework for the detection of and response to international public health risks and potential public health emergencies of international concern.

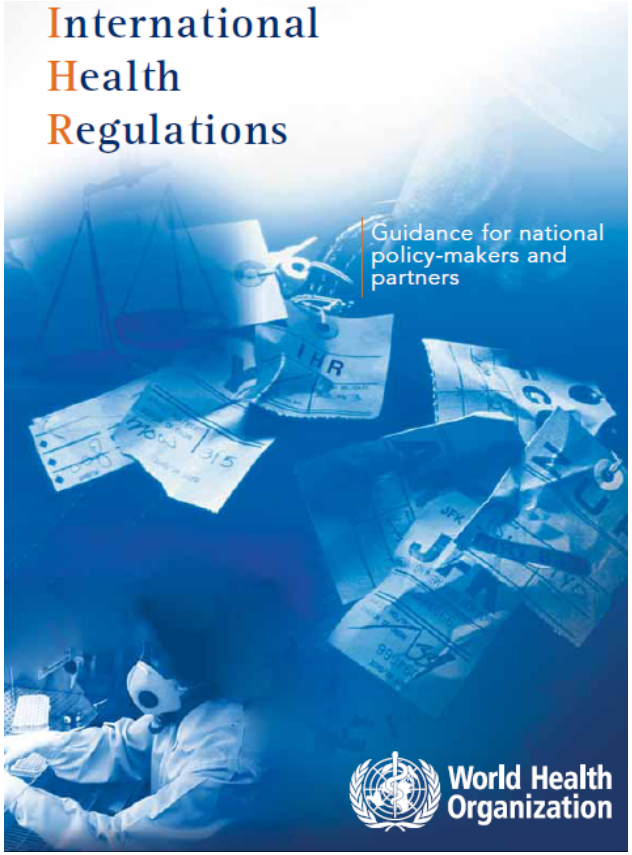
- Each State Party has new obligations to prevent and control the spread of disease inside and outside their borders, **and to report potential public health emergencies of international concern to WHO**. To this end, your country is expected to develop and maintain its key disease surveillance capabilities.

- As a State Party to the IHR(2005), your country benefits from WHO's surveillance activities and from WHO's reports from other States Parties of critical health risks that may affect your country. States Parties may also participate in coordinated response efforts to protect your country from these fast-traveling risks.

- WHO is mandated to assist States Parties in fulfilling these new obligations.

- The IHR(2005) also offer new opportunities to countries to strengthen their public health capacities and collaborate with each other and with WHO.





For further information visit www.who.int/ihr or contact your WHO Regional Office

Knowledge Check

The International Health Regulations (2005) only apply to natural disease outbreaks

TRUE **FALSE**

The IHRs (2005) apply to <u>any diseases and public health events (biological, chemical, radiological)</u>, including those from new or unknown causes, irrespective of origin or source, that could present significant harm to humans.

Natural disease outbreak | Unintended consequences | Accidents | Negligence | Vandalism / sabotage | Deliberate use of BW

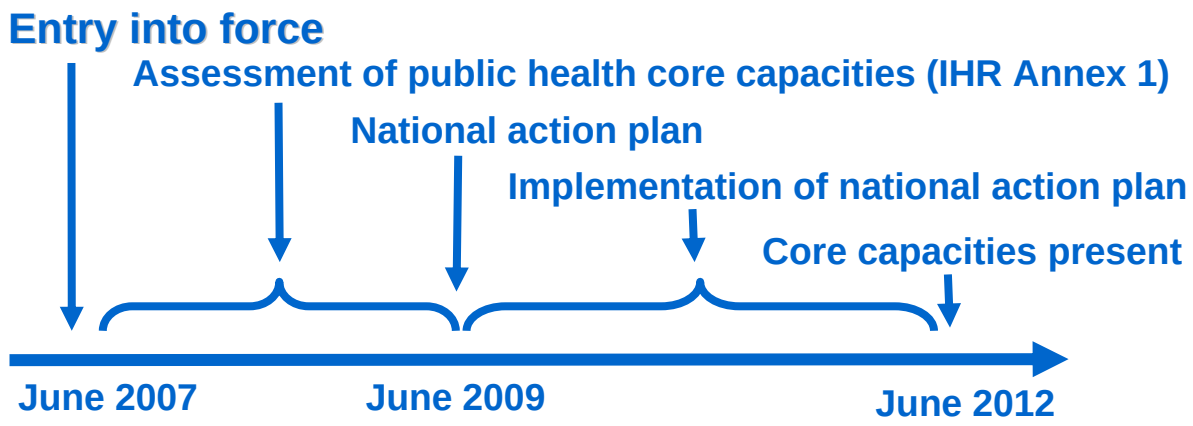
Requirements of the International Health Regulations

Annex 12: ***"Each State Party shall develop, strengthen and maintain, as soon as possible but no later than 5 years from the entry into force… the capacity to detect, assess, notify and report events in accordance with these Regulations"***

Annex 1: ***"the capacity to respond promptly and effectively to public health risks & public health emergencies of international concern…"***

Article 54: ***States Parties and WHO are required to report to the WHA on a yearly basis on progress made in the implementation of the Regulations***

8 Core capacities
- Legislation and Policy
- Coordination
- Surveillance
- Response
- Preparedness
- Risk Communications
- Human Resources
- Laboratory

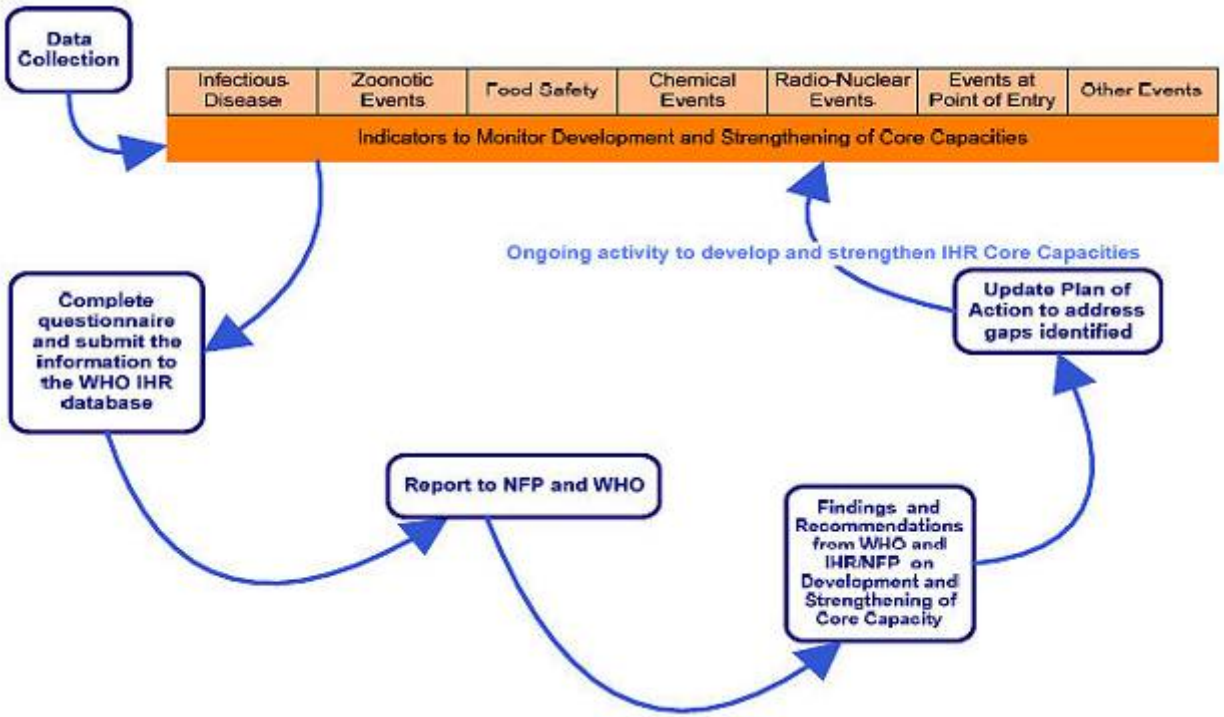


Laboratories & the IHRs

"Laboratory" or "specimens" is quoted 7 times in the text

1. Detection → **laboratory data to be reported (annex 1)=early warning signal**
2. Assessment of events → **insufficient laboratory capacity = serious event (annex 2)**
3. Public health response supported through the **laboratory analysis of samples, domestically or through collaborating centres** (annex 1)
4. Notification to WHO → **continuous communication of laboratory results (art. 6)**
5. Information sharing → **links with …laboratories for the dissemination of information** and recommendations (annex 1)
6. Recommendations by WHO with respect to the persons may include the review of **laboratory analysis** (art. 18)
7. Facilitating the **transport and handling of biological substances, reagents and materials** for diagnostic purposes (art. 46)

Framework & processes for monitoring the development of national core capacities



IHR Monitoring Framework: Checklist and Indicators for Monitoring Progress in the Development of IHR Core Capacities in States Parties (WHO/HSE/IHR/2010.1)

Framework of:

- **20 <u>mandatory</u> global indicators** for annual reporting to the WHA by all States Parties
- **10 <u>optional</u> indicators**

Tools for monitoring:

- **Checklist**
- **Indicators**
- **Questionnaire**

Core Capacity 8: Laboratory

IHR (2005) Annex 1, paragraph 6(b):

"Public health response to provide support through specialized staff, laboratory analysis of samples (domestically or through collaborating centres) and logistical assistance (e.g. equipment, supplies and transport"

Core Capacity 8: Laboratory[87]					
Component of core capacity	**Country level indicator**	**Current status of implementation of core capacities**			
		<1 Prerequisites	**1 Inputs and process**	**2 Outputs and outcomes**	**3 Additional achievements**
Laboratory diagnostic and confirmation capacity	**Laboratory services are available and accessible to test for priority health threats.**	Policy to ensure quality of laboratory diagnostic capacity (e.g., licensing, accreditation etc.).	An updated and accessible inventory of public and private laboratories[88] and their relevant diagnostic capacity is available. National reference laboratory(ies) (NRL) designated and list of NRL disseminated to relevant stakeholders. Access to diagnostic services[89] for priority diseases, for pathogens listed in Annex 2 of the IHR (2005), and for public health threats including hazardous substances[90]. National or international external quality assessment schemes are implemented for diagnostic laboratories in the country for major public health disciplines[91].	Network of national and international laboratories established to meet diagnostic and confirmatory laboratory requirements and support outbreak investigations for events specified in Annex 2 of IHR (2005). Greater than 10 non-AFP hazardous specimens per year referred to **national** or international reference laboratories for examination. Laboratory test results are received from the diagnostic laboratory in a timely[92] manner to inform decision-making and actions.	All diagnostic laboratories are certified or accredited according to international standards[93], or to national standards adapted from international standards. A national system is in place for reliable and safe detection of MDR and XDR[94] *M. tuberculosis*, with quality assurance results available for peer review and dissemination. Country has one or more National Reference Laboratory contributing to diagnostic services in another country.

WHA Indicators:

12. Laboratory services to test for priority health threats are available and accessible.
13. Laboratory biosafety and biosecurity practices are in place.

WHO Questionnaire / Annual Reporting

Core Capacity:	Laboratory
Component:	8.2 Laboratory biosafety and Biosecurity
Indicator:	8.2.1 Laboratory biosafety and Biosecurity practices are in place.

8.2.1.1 Are biosafety guidelines accessible to individual laboratories?

8.2.1.2 Do regulations, policies or strategies [73] exist for laboratory biosafety?

8.2.1.3 Has a responsible entity [74] been designated for laboratory biosafety and biosecurity?

8.2.1.4 Have biosafety guidelines, manuals or SOPs been disseminated to laboratories?

8.2.1.5 Are relevant staff trained on biosafety guidelines?

8.2.1.6 Has national classification of microorganisms by risk group [75] been completed?

8.2.1.7 Is there an institution or person [76] responsible for inspection, (could include certification of biosafety equipment) of laboratories for compliance with biosafety requirements?

8.2.1.9 Has a biorisk [77] assessment been conducted in laboratories to guide and update biosafety regulations, procedures and practice, including for decontamination and management of infectious waste?

8.2.1.10 Are diagnostic laboratories designated and authorized or certified BSL 2 or above for relevant levels of the health care system?

8.2.1.11 Have country experience and findings related to biosafety been evaluated and reports shared with the global community?

WHO Resources for Technical Assistance on Biosafety / Biosecurity

World Health Organization

Health topics | Data and statistics | Media centre | Publications | Countries | Programmes and projects | About WHO

Search | Advanced search

International Health Regulations (IHR)

- International Health Regulations
- About the IHR
- Partnerships
- National surveillance and response
- Ports, airports and ground crossings
- Global alert and response
- Specific risks
- Legal issues and monitoring

Biosafety and laboratory biosecurity

Background

Collaborating Centres, Biosafety Advisory Group (BAG) and other partners

Key activities

Information resources, publications

Mission

The WHO Biosafety and Laboratory Biosecurity programme provides guidance on and promotes the use of safe and secure workplace practices, appropriate protective equipment, engineering and administrative controls in the handling of pathogenic organisms in laboratories, during transportation, in field investigations and in vaccine manufacturing facilities, to protect workers, the environment and the community from exposure, infection, and subsequent development of disease.

Goals and Objectives

Assist Member States understand, adopt and implement biorisk management strategies to minimize risks of infections through safe and secure practices in laboratory and transport environments, and to accomplish these goals in a cost-effective manner Establish a biosafety and laboratory biosecurity culture worldwide

Vision

Development of a cross-cutting coordinated WHO strategy for biosafety and laboratory biosecurity supporting vertical disease-specific programmes and activities, to promote the harmonization and implementation of biorisk management principles and strategies.

IHR Lyon office

International Health Regulations Coordination WHO Lyon Office

Lyon-office: Ten year anniversary

Highlights

IHR i-course: Apply here

Symposium: Securing global health in the 21st century
29 March 2011

IHR training site: online modules on the IHR

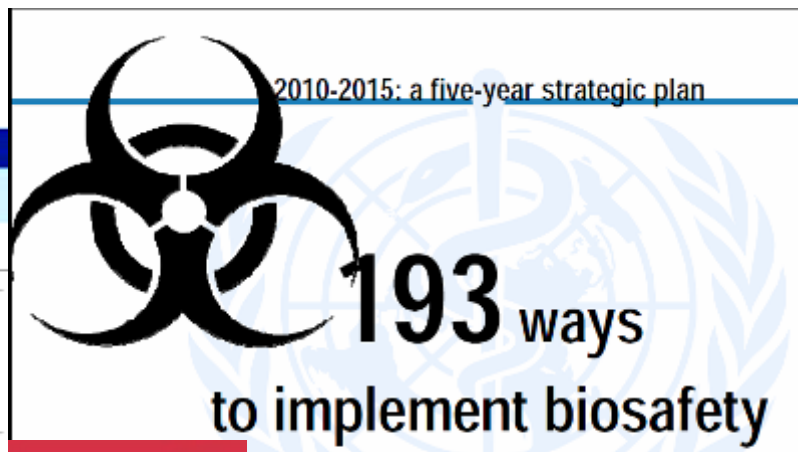
Securing global health: Second IHR implementation course

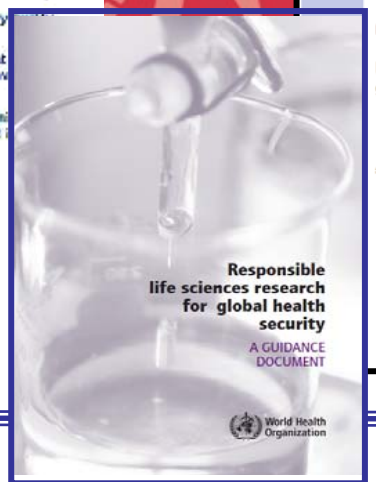
Biosafety and laboratory security

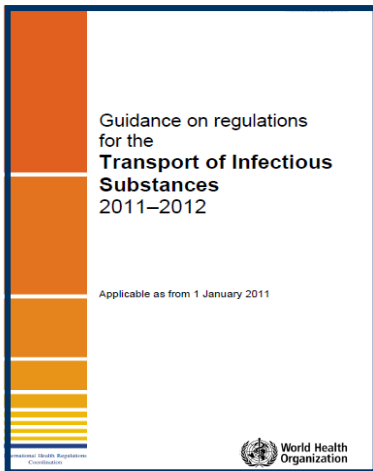
Training toolkit: Laboratory management system

IHR implementation at and groundcrossings [www 00:03:37]

E-library: Knowledge, train resources to support IHR







http://www.who.int/ihr/biosafety/en/index.html

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BWC Key Facts and Provisions

- ***Convention on the Prohibition of the Development, Production, and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction (BWC)***

- ***Article I:*** States Parties *"never in any circumstances to* ***develop, produce, stockpile or otherwise acquire or retain****: (1) Microbial or other biological agents, or toxins whatever their origin or method of production, of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes; (2) Weapons, equipment or means of delivery designed to use such agents or toxins for hostile purposes or in armed conflict"*
  - The **prohibition of the use of BW** - originating in the *1925 Geneva Protocol for the Prohibition of the Use of Asphyxiating, Poisonous or other Gases, and of Bacteriological Methods of Warfare,* also falls under the purview of BWC (specifically under Article I), as stated at the 4th BWC Review Conference

- ***Article III:*** States Parties to refrain from **transferring BW** to anyone and from **assisting, encouraging or inducing** anyone to manufacture or acquire them

- ***Article IV:*** ***prescribes obligations for States Parties to implement the BWC through appropriate national measures including legislative, regulatory or any appropriate penal laws that prevent the proliferation of dual-use products and technology for illicit weapon purposes to States as well as non-State actors***

Knowledge Check

Is there a list of biological agents controlled under the BWC?

NO

"Almost any disease-causing organism (such as bacteria, viruses, fungi, prions or rickettsiae) or toxin (poisons derived from animals, plants or microorganisms, or similar substances synthetically produced) can be used in biological weapons"
(BWC)

"Any micro-organism, virus, infectious substance, or biological product that may be engineered as a result of biotechnology, or any naturally occurring or bioengineered component of any such microorganism, virus, infectious substance, or biological product, capable of causing death, disease, or other biological malfunction in a human, an animal, a plant, or another living organism; deterioration of food, water, equipment, supplies, or material of any kind..."

(US BW Anti-Terrorism Act of 1989 / US Code Title 18, Part I, Ch.10)

Conference on Disarmament
Anti-Personnel Landmines Convention
The Biological Weapons Convention
The Convention on Certain Conventional Weapons
Convention on Cluster Munitions
Disarmament Fellowship
Other Issues Related to Disarmament
Disarmament Resource Guides

Disarmament

BWC Compendium of National Approaches to Biosafety & Biosecurity

This page provides information on national approaches to biosafety and biosecurity, as provided to the Implementation Support Unit by States Parties. It was created as a resource for the 2008 meetings of the BWC.

In his letters to States Parties, the Chair of the 2008 meetings requested "a brief outline or overview" of national approaches to the topics under consideration "to optimise our use of time". He went on to add that this was not "extra or additional information, or... any kind of reporting requirement" but that the compendium was a tool to enable information generated by meetings of the BWC to be shared in a more efficient manner and more readily accessible to assist States Parties in their preparations for the meetings, during their national activities and in preparation for the Seventh Review Conference and future efforts.

The ISU has information on:

- Australia
- Brazil
- Bulgaria
- Canada
- Georgia

BWC ISU website reference: http://www.unog.ch/bwc

BWC Confidence Building Measures (CBMs)

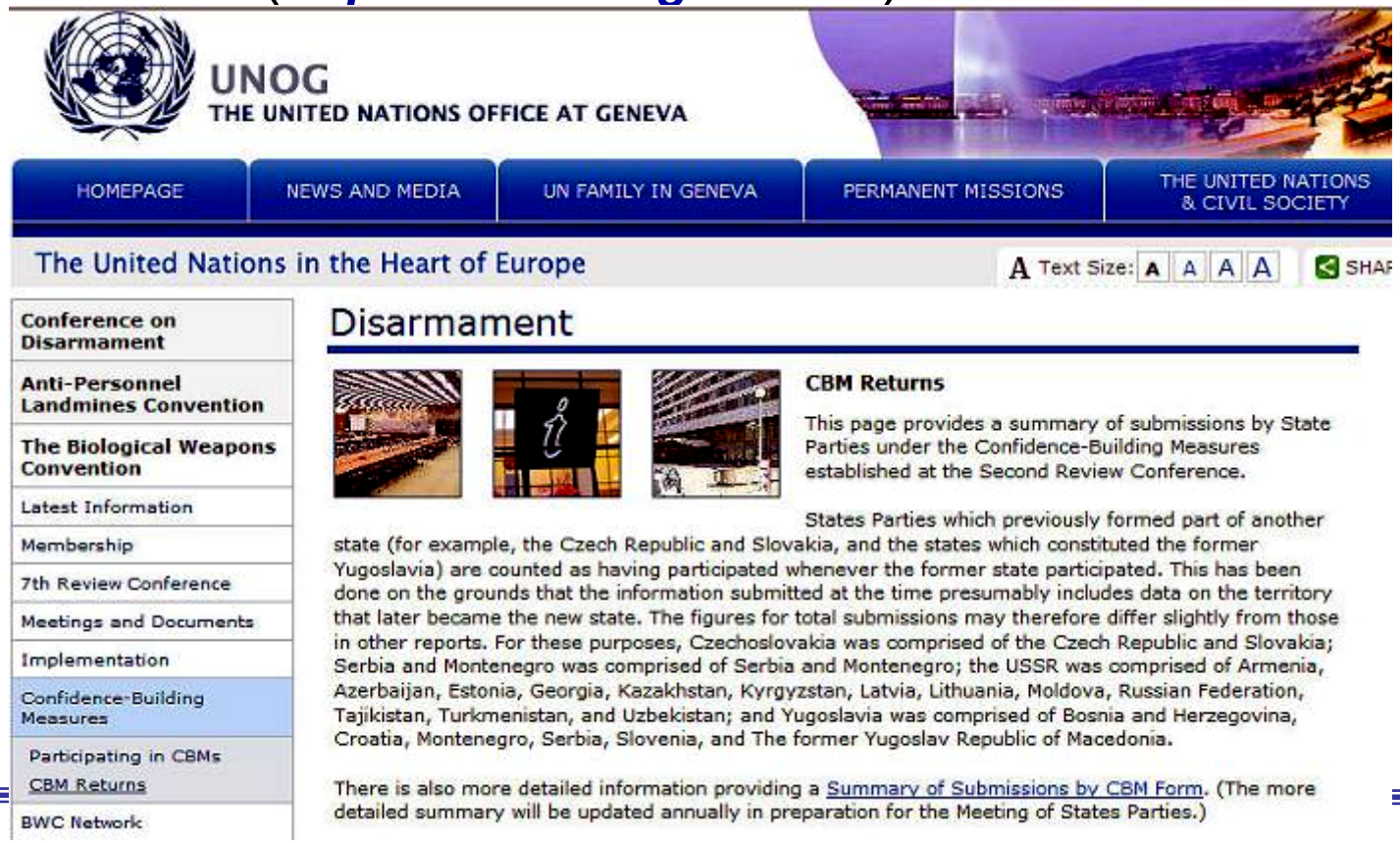
- 1986 agreement: introduce CBMs ***"in order to prevent or reduce the occurrence of ambiguities, doubts and suspicions and in order to improve international cooperation in the field of peaceful biological activities"***
- CBMs were elaborated in 1987 and modified/expanded in 1991; submission / distribution improved in 2006
- CBMs (on agreed forms) are submitted to the BWC ISU no later than **15 April each year**
- CBMs are not legally-binding (i.e. not required by any article of the Convention)

CBM A	**Part 1: Exchange of data on research centers and laboratories**	
	Part 2: Exchange of information on national biological defense research and development programs	**Part 2(i): National biological defense research and development programs- Declaration**
		Part 2(ii): National biological defense research and development programs- Description
		Part 2(iii): National biological defense research and development programs- Facilities
CBM B	**Exchange of information on all outbreaks of infectious diseases and similar occurrences caused by toxins**	**(i): Background information on outbreaks of reportable infectious diseases**
		(ii): Information on outbreaks of infectious diseases and similar occurrences that seem to deviate from the normal pattern
CBM C	**Encouragement of publication of results and promotion of use of knowledge**	
CBM D	**Active promotion of contacts**	**1: Planned international conferences, symposia, seminars, and other similar fora**
		2: Information regarding other opportunities
CBM E	**Declaration of legislation, regulations and other measures**	
CBM F	**Declaration of past activities in offensive and/or defensive biological research and development programs**	
CBM G	**Declaration of vaccine production facilities**	

CBMs transparency

- CBMs are posted in the *password-protected area of the BWC ISU website* (reserved for the use of official representatives of BWC States Parties only), unless the submitting State Party requests otherwise

- Certain States have decided to make their CBMs available on the *public section of this site* (***http://www.unog.ch/bwc***)



Confidence-Building Needs Transparency

- ***"The Obama administration's new strategy for countering biological threats—both natural and man-made—rests upon the main principle of the BWC: that the use of BW is "repugnant to the conscience of mankind"***

  - U/S Tauscher unveiling the **US National Strategy for Countering Biological Threats** at the 2009 BWC Meeting of States Parties

- ***"in a gesture of our transparency", the United States will "work toward posting future annual CBM submissions on the public access side of the Implementation Support Unit website and we will encourage other Parties to follow suit"***

  - Ellen Tauscher, U/S of State for Arms Control

- US CBMs posted publicly in 2010 & 2011

09 Dec 2009: U.S. Under Secretary of State for Arms Control, Ellen Tauscher, addresses the BWC

http://geneva.usmission.gov/2009/12/09/tauscher-bwcl

On the Front Line of Biodefense

Biological Risk Management and Non-Proliferation Activities Supported by the Office of the Assistant Secretary for Preparedness and Response

The 1972 Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction, commonly known as the Biological Weapons Convention (BWC), was the first international treaty to completely prohibit the development, production and stockpiling of an entire class of the biological weapons. By ratifying the Convention, States Parties proclaim their determination "to exclude completely the possibility of bacteriological (biological) agents and toxins being used as weapons" and their conviction that "such use would be repugnant to the conscience of mankind and that no effort should be spared to minimize this risk".

The central prohibitions of the treaty are stated in Article I: "Each State Party to this Convention undertakes never in any circumstances to develop, produce, stockpile or otherwise acquire or retain: (1) Microbial or other biological agents or toxins whatever their origin or method of production, of types and in quantities that have no justification for prophylactic, protective, or other peaceful purposes; (2) Weapons, equipment or means of delivery designed to use such agents or toxins for hostile purposes or in armed conflict".

The risk of biological warfare and bioterrorism has increased but so has the determination of the United States to prevent, deter, and mitigate them, as illustrated by the President's National Strategy for Countering Biological Threats. When unveiling the Strategy at the BWC Meeting of States Parties in December 2009, the Under Secretary for Arms Control Ellen Tauscher, stated that "The Obama administration's new strategy for countering biological threats—both natural and man-made—rests upon the main principle of the BWC: that the use of biological weapons is repugnant to the conscience of mankind".

The U.S. Department of Health and Human Services, through its staff and operational divisions, is committed to helping countries build sustainable public health systems to counter biological threats, whether natural or man-made, and leverage key multilateral organizations such as BWC to strengthen strategic partnerships and coordination for global health security.

Biodefense Resources

Key Resources

- United States Mission in Geneva
- Biological Weapons Convention
- 1540 Committee
- National Select Agent Registry
- Biodefense
- CBRN Activities
- National Science Advisory Board for Biosecurity
- Countering Biological Threats: National Implementation of the Biological Weapons Convention and Multinational Outbreak Response and Bioterrorism Investigation Demonstration

Confidence-Building Measures

- 2010 CBM Return
- 2009 CBM Return

ASPR website at: *http://www.PHE.gov/about/OPP/Pages/bwc.aspx*

Opportunities to Report on Biosafety / Biosecurity in CBMs

- **Biosafety and biosecurity provisions: critical in BWC implementation** (which may include *inter alia* legislative, regulatory, policy, and other measures to enhance domestic implementation & compliance with the BWC; national export control systems; education, awareness raising & outreach; disease surveillance, detection & containment)

- **CBM E (*Declaration of legislature, regulations, & other measures*):** relevant laws, regulations, or other measures on biosafety / biosecurity national framework

- **CBM A Part 2(ii) *(National biological defense research and development programs- Description)*:** address oversight roles & responsibilities

- **CBM B (ii) *(Information on outbreaks of infectious diseases and similar occurrences that seem to deviate from the normal pattern)*:** report disease outbreaks when… *inter alia*, "*the disease occurs in the vicinity of research centres and laboratories subject to exchange of data under item [CBM Form] A..*"

- **CBM C (*Encouragement of publication of results and promotion of use of knowledge*):** report relevant policies, publications, reports, etc

- **CBM D (*Active promotion of contacts*):** relevant educational and training activities

Biosafety / Biosecurity in CBMs - submission examples -

United States of America

Confidence Building Measure Return covering 2010

Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction

Submitted to the United Nations on
April 15, 2011

http://www.PHE.gov/about/OPP/Pages/bwc.aspx

Form A, Part 2 (ii)

National biological defence research and development programme

Overview of HHS Biodefense Programs and Activities

Improving our nation's defenses against biological threats is a key part of the U.S. Government's homeland security effort. The U.S. Department of Health and Human Services (HHS) supports activities to improve local and state public health systems, to expand existing biosurveillance efforts, and to fund research on medical countermeasures against potential bioterror agents. HHS also has a key role in implementing the Biological Weapons Convention (BWC) tenets and the United Nations Security Council Resolution 1540 (UNSCR 1540) through a legal, extant, regulatory, and policy framework on biological risk management, and effective oversight of its biodefense programs. Many different divisions within HHS have a role in these diverse activities.

The main operating divisions of HHS involved in biodefense are: CDC (Centers for Disease Control and Prevention), NIH (National Institutes of Health), and FDA (Food and Drug Administration). The staff divisions primarily involved in biodefense issues are the Assistant Secretary for Preparedness and Response (ASPR) and the Office of Global Health Affairs (OGHA). For complete list of HHS staff and operating divisions, please see: http://www.hhs.gov/open/contacts/index.html#od

Within ASPR, the Office of Policy and Planning (OPP) advises HHS and ASPR leadership on policy options and strategic planning to support domestic and international public health emergency preparedness and response activities within ASPR, HHS, and the Federal Government. OPP serves as the focal point for the National Security Staff (NSS) policy coordination activities on behalf of ASPR and leads the development and implementation of an integrated ASPR approach to policy. On behalf of HHS, ASPR is supporting the U.S. Department of State in its public diplomacy demarches related to the Biological Weapons Convention (BWC), represents HHS in the U.S. delegation to the BWC, coordinates the HHS reporting on CBMs, and it has a key role in implementing the BWC tenets through a legal, extant, regulatory, and policy framework on biological risk management, and effective oversight of its biodefense programs.

Biosafety / Biosecurity in CBMs - submission examples -

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Submitted to the United Nations on
April 15, 2011

http://www.PHE.gov/about/OPP/Pages/bwc.aspx

FORM C

Encouragement of Publication of Results and Promotion of Use of Knowledge

U.S. Department of Health and Human Services (HHS) Open Government Plan and the HHS Strategic Plan 2010-2015

The U.S. Department of Health and Human Services (HHS) Open Government Plan represents the official response of the U.S. Department of Health and Human Services (HHS) to the White House's Open Government Directive, issued on December 8, 2009. The plan embraces the idea of working proactively and energetically to advance a culture of Open Government at HHS.

HHS believes that transparency and data sharing are of fundamental importance to its ability to achieve its strategic goals of advancing the health and well-being of the United States. HHS's vast stores of data are a remarkable resource which can be utilized to help citizens understand what HHS does and hold it accountable, help the public hold the private sector accountable, increase awareness of health and human services issues, generate insights into how to improve health and well-being, spark public and private sector innovation and action, and provide the basis for new products and services.

The National Institutes of Health (NIH) Review Mechanism for Dual Use Research Manuscripts

The NIH has established a review mechanism for manuscripts which may involve dual use research of concern.

The Publication and Abstract Clearance Form is available online at:
http://www1.od.nih.gov/oir/sourcebook/oversight/pub-clear-form.htm

The Dual Use Questionnaire is available online at:
http://sourcebook.od.nih.gov/oversight/Dual%20Use%20Questionnaire-4-2010.pdf

CDC Policy on oversight and clearance of dual use research of concern is available online at:
http://www.cdc.gov/OD/foia/policies/policy516.pdf

Biosafety / Biosecurity in CBMs - submission examples -

United States of America

Confidence Building Measure Return covering 2010

Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction

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Form D

Active promotion of contacts

1. Planned international conferences, symposia, seminars, and other similar forums for exchange

May 17-20, 2011
Countering Biological Threats: National Implementation of the Biological Weapons Convention and Multinational Outbreak Response and Bioterrorism Investigation Demonstration
Tbilisi, Georgia
The U.S. Department of Defense and the U.S. Department of Health and Human Services will hold a conference and functional exercize in Tbilisi, Georgia, for civilian and military public health, law enforcement, military, and affiliated professionals from 10 countries as well as representatives of inter-governmental organizations (WHO, INTERPOL, NATO, UN Office of Disarmament Affairs (UNODA), and the Biological Weapons Convention (BWC) Implementation Support Unit).

October 27-November 2, 2011
54th Annual Biological Safety Conference (non-government)
Anaheim, CA
The 54th Annual Biological Safety Conferences is sponsored by the American Biological Safety Association (ABSA). The 2011 Conference will feature:

- Four Full Days of Intensive Pre-Conference Courses
- Three Full Days of State of the Art Keynotes, Papers, and Panels
- Exhibits Showcasing the Latest in Laboratory Biosafety Products and Services
- Invaluable Networking with Biosafety Professionals

For more information, please visit:
http://www.absaconference.org/

This conference is not being hosted by the U.S. Government, but U.S. Government researchers and grantees will likely participate.

Form D

Active promotion of contacts

2. Information regarding other opportunities

Dual Use Concerns in Life Sciences Research
The National Institutes of Health (NIH) released a new educational video in June 2010 on the topic of dual use research in the life sciences. The video was developed to promote awareness and understanding about the dual use research issue by offering a conceptual overview through interviews with nationally respected scientists, institutional leaders, journal editors, and a member of the public. Discussants describe the need to ensure scientific progress while attending to scientific responsibility and important oversight and security concerns. The video is available on the Dual Use Program page of the Web site of the NIH Office of Biotechnology Activities (OBA, http://oba.od.nih.gov/biosecurity/biosecurity.html), as well as YouTube

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Final Rule Stage: Possession, Use, and Transfer of Select Agents and Toxins: Chapare Virus (Chapter 610 Review)
Action: Final Action 11/00/11

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 authorizes the HHS Secretary to regulate the possession, use, and transfer of select agents and toxins that have the potential to pose a severe threat to public health and safety. These regulations are set forth at 42 CFR 73. Criteria used to determine whether a select agent or toxin should be included under the provisions of these regulations are based on: (1) The effect on human health as a result of exposure to the agent or toxin, (2) the degree of contagiousness of the agent or toxin, (3) the methods by which the agent or toxin is transferred to humans, (4) the availability and effectiveness of pharmacotherapies and immunizations to treat and prevent and illness resulting from infection by the agent or toxin, and (5) any other criteria, including the needs of children and other vulnerable populations that the HHS Secretary considers appropriate. Based on these criteria, we are proposing to amend the list of HHS select agents and toxins by adding Chapare virus to the list. After consulting with subject matter experts from CDC, the National Institutes of Health (NIH), the Food Drug Administration (FDA), the United States Department of Agriculture (USDA) /Animal and Plant Health Inspection Service (APHIS), USDA/Agricultural Research Service (ARS), USDA/CVB (Center for Veterinary Biologics), and the Department of Defense (DOD)/United States Army Medical Research Institute for Infectious Diseases (USAMRIID) and review of relevant published studies, we believe the Chapare virus should be added to the list of HHS select agents and toxins based on our conclusion that the Chapare virus has been phylogenetically identified as a Clade B arenavirus and is closely related to other South American arenaviruses that cause haemorrhagic fever, particularly Sabia virus.

Form E

Declaration of legislature, regulations and other measures relating to

	Legislation	Regulations	Other	Amended Since Last year
Development, production, stockpiling, acquisition or retention of microbial or other biological agents, or toxins, weapons, equipment and means of delivery specified in Article I	YES	YES	YES	YES
Import of Micro-Organisms and Toxins.	YES	YES	YES	NO
Export of Micro-Organisms and Toxins.	YES	YES	NO	YES

Synthetic Biology Program
To address the potential misuse of technological advances that enable the synthetic generation of DNA sequences, the FBI has partnered with HHS, USDA, DOS, Department of Commerce (DOC), DHS, and the synthetic DNA industry to develop a mechanism to report, respond to, and investigate suspicious purchase requests of potentially harmful DNA sequences. Working with industry, procedures have been developed to screen unusual purchases, including those that may involve sequences associated with Select Agents, to create a reporting mechanism for suspicious orders that may pose a threat.

Compliance Reporting at the BWC Review Conferences

"...The Conference decides that the **7th Review Conference shall be held in Geneva not later than 2011** and should review the operation of the Convention, taking into account, *inter alia*:

- (i) new scientific & technological developments relevant to the Convention;
- ***(ii) the progress made by States Parties on the implementation of the obligations under the Convention;***
- (iii) progress of the implementation of the decisions & recommendations agreed upon at the 6th Review Conference".

Final Report of the Sixth Review Conference of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction (BWC/CONF.VI/6)

- **Types of information** previously provided by States Parties:
  - Information structured by the articles of the Convention
  - Thematic approach (i.e. information on specific types of activities that address how they translate their obligations into national action)
  - 3% of past submissions focused entirely on national implementation legislation
- **Areas covered:**
  - National & international activities
  - Participation
  - <u>Collaboration and assistance</u>

Tip for reporting on collaboration & assistance: Synergy of IHRs Article 44 & BWC Article X

Compliance Reporting at the BWC Review Conferences

11. Aspects of national activities covered in compliance reports submitted by States Parties have included:

(a) The presence of relevant national laws and regulations, as well as a summary of measures and arrangements or a link to their text;

(b) The existence of a National Point of Contact;

(c) The presence of an export (and import) control regime, as well as a summary of measures and arrangements or a link to their text;

(d) The presence or absence of any biodefence activity, as well as a summary of activities or a link to additional information;

(e) The presence of biosafety and biosecurity regimes, or efforts to strengthen such capacity, as well as a summary of measures, arrangements and activities or a link to additional information;

(f) The presence of education and outreach activities with the life sciences (including codes of conduct), as well as a summary of activities or a link to additional information;

(g) Interactions with industry and the private sector, as well as a summary of activities or a link to additional information;

(h) The presence of disease surveillance regimes, or efforts to strengthen such capacity, as well as a summary of measures and arrangements or a link to additional information; and

(i) The presence of an emergency response capacity that might be used following the use of a biological weapon, or efforts to strengthen such capacity, as well as a summary of measures and arrangements or a link to additional information.

Information provided to past review conferences on compliance by States Parties with their obligations under the Convention - Submitted by the Implementation Support Unit,

available online at: http:www.unog.ch/bwc

Other opportunities for reporting on national implementation of BWC: domestic visits

Trip to HPA Porton Down, March 2011 (Click for larger size)

Trip to DSTL Porton Down, March 2011 (Click for larger size)

Trip to the US National Biodefence Analysis and Countermeasures Center, July 2011

Trip to the US National Institute of Allergy and Infectious Diseases Integrated Research Facility, July 2011

Website of the President-designate of the Seventh Review Conference of the Biological Weapons Convention:

http://www.unog.ch/80256EE600585943/(httpPages)/7EF0D5B39D1D0FCFC125782400403D1C?OpenDocument

Biosafety / Biosecurity = Cross-Cutting, Vital Elements of Health Security & Biological Non-Proliferation

	WHO IHRs (2005)	BWC	UNSCR 1540
Applicability:	**All 193 WHO States Parties**	**164 BWC States Parties**	**All 193 UN Member States**
Purpose:	**"to prevent, protect, protect against, control and provide a public health response to the international spread of disease…"**	**To prohibit the development, production, acquisition, transfer, stockpiling and use of biological and toxin weapons**	To **prohibit non-State actors** from developing, acquiring, manufacturing, possessing, transporting, transferring or using nuclear, chemical or biological weapons and their delivery systems
Requirements:	Capacities *"to detect, assess, notify, and report events"* & *"respond promptly & effectively to public health risks & PHEICs"* [Lab core capacity includes biosafety / biosecurity]	***Any necessary measures to prohibit and prevent the development, production, stockpiling, acquisition, retention, transfer or use of biological weapons***	Domestic controls to prevent the proliferation of nuclear, chemical and biological weapons, their means of delivery, and related materials
Entry into force:	**15 June 2007**	**26 March 1975**	**28 April 2004**
Mandated reporting / where / when:	Status of implementation / WHO / *"As soon as possible but no later than five years from entry into force …"; annual reporting on indicators*	***None**** **** CBM voluntary reporting / BWC ISU / every year by 15 April***	Status of implementation / 1540 Committee / *"without delay"*

United Nations Security Council Resolution 1540 (UNSCR 1540)

- [BWC States Parties] ***"recognized the contribution of full and effective implementation of United Nations Security Council Resolution 1540 by all states to assist in achieving the objectives of this Convention"-*** *The Solemn Declaration of BWC States Parties at the 6th Review Conference*

- UNSCR 1540 was adopted in 2004 under Chapter VII of the UN Charter and as such, it is binding on all Member States of the United Nations, regardless of their membership in multilateral agreements

- **The main obligations are contained in Operative Paragraphs (OP) 1 to 3**
  - **OP1** prohibits States to provide *"any form of support to non-State actors that attempt to develop, acquire, manufacture, possess, transport, transfer or use nuclear, chemical or biological weapons and their means of delivery."*
  - **OP2** requires States to adopt and enforce appropriate and effective laws to prohibit such activities under their national legislation
  - **OP3** prescribes that UN members implement and enforce a comprehensive system of domestic controls on WMD and related materials

UNSCR 1540 reporting

- All States are called upon to report to the 1540 Committee on **steps they have taken or intend to take to implement the provisions of OP 1, 2 and 3**

- All States are also called upon to include in their national reports, as appropriate, **information relating to the implementation of OP 6,7,8, 9 and 10** of UNSCR 1540

- UNSCR 1810 (2008) calls upon all States that have not yet presented a first report on steps they have taken or intend to take to implement UNSCR 1540 to submit such a report to the 1540 Committee **without delay;** States to provide, **at any time or upon request of the 1540 Committee**, additional information

- States are encouraged to **prepare on a voluntary basis summary action plans** mapping out their priorities and plans for implementing UNSCR 1540

Requirements for the domestic control of BW related materials & means of delivery

- Measures to account for/secure production, use, storage, & transport
- Regulations for physical protection of facilities/ materials/ transports
- Licensing/registration of facilities/people handling biological materials
- Reliability check of personnel
- Measures to account for/secure/physically protect means of delivery
- Regulations for genetic engineering work
- Other legislation/ regulations related to safety and security of biological materials

- **The 1540 Matrix** (adopted in 2005) is the primary method used by the 1540 Committee to organize information about implementation of UNSCR 1540 by Member States

- **A matrix for each UN Member State** has been prepared; matrices are regularly updated and approved by the Committee

- The 1540 Committee uses the matrices as a **reference tool** to examine the status of implementation of UNSCR 1540 and in its dialogue with States as a tool to identify gaps existing at national level and facilitate technical assistance

1540 COMMITTEE

Security Council Committee established pursuant to resolution 1540 (2004)

http://www.un.org/sc/1540

Search

List of National Reports by Submitting Member States

A B C D E F G H I J K L M N O P Q R S T U V W X Y Z

OTHER SUBMISSION

Submitting State	Date of submission	Symbol
Afghanistan	28 August 2008	S/AC.44/2004/(02)/139
Albania	28 October 2004	S/AC.44/2004/(02)/38
Algeria	10 November 2004 7 September 2005 30 April 2008	S/AC.44/2004/(02)/73 Add.1 S/AC.44/2007/1
Andorra	27 October 2004 31 October 2005 13 March 2008	S/AC.44/2004/(02)/19 Add.1 Add.2

1540 COMMITTEE

Security Council Committee established pursuant to resolution 1540 (2004)

http://www.un.org/sc/1540

Search

Other National Documents

Canada	12 August 2010	Action Plan for the implementation of Resolution 1540 (2004)
Argentina	17 March 2009	Action Plan for the implementation of Resolution 1540 (2004)
France	25 June 2008	Note Verbale from the Permanent Mission of France to the United Nations
United States of America and Portugal on behalf of European Union	26 July 2007	Joint letter transmitting extract from US-EU Summit's Declaration on Promotion of Peace, Human Rights and Democracy Worldwide *
United States of America	20 April 2007	Action Plan for Implementation of Resolution 1540 (2004)

OP 2 - Biological Weapons (BW)

State:	United States of America
Date of Report:	12 October 2004
Date of Addendum 1:	13 September 2005
Date of Addendum 2:	21 December 2007
Date of Addendum 3:	8 January 2008

Does national legislation exist which prohibits persons or entities to engage in one of the following activities ? Can violators be penalized ?		National legal framework		Enforcement: civil/criminal penalties and others		Remarks
		YES	if YES, indicate source document of national implementation law	YES	if YES, indicate source document	
1	manufacture/produce	X	1. Biological Weapon Anti-Terrorism Act of 1989, as amended (18 USC § 175) 2. Antiterrorism and Effective Death Penalty Act of 1996. 3. Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act of 2001 (USA PATRIOT Act) . 4. Public Health Security and Bioterrorism Preparedness and Response Act of 2002. 5. Agricultural Bioterrorism Protection Act of 2002	X	1. Crimes and Criminal Procedure, 18 USC § 175, 175(a), 175(c), 176, and 177 2. Civil Affairs Forfeiture Reform Act (CAFRA)	
2	acquire	X		X		
3	possess	X		X	1. Crimes and Criminal Procedure, 18 USC § 175, 175(a), 175(b), 175 (c), 176, and 177	
4	stockpile/store	X		X	1. Crimes and Criminal Procedure, 18	
5	develop					
6	transport					
3	Assistance offered			X	1. The United States submitted its Action Plan for Implementation of Resolution 1540 (2004) in April 2007 (http://www.un.org/sc/1540/nationaldocuments.shtml). The Action Plan focuses on offering and facilitating assistance related to implementation of the resolution. The United Sates maintains many assistance programs (see line 5 below), and has made several presentations on offering assistance. 2. In 2009, the United States announced that the Center for Disease Control will soon become the world's first World Health Organization Collaborating Center for implementing International Health Regulations, where it will assist the WHO and other international partners to help build the necessary global infrastructure to fully implement the IHRs in all six WHO Regions. 3. In 2010 DHHS/DOD conducted two multi-national workshops with associated tabletope exercises (The Southern Caucasus Workshop on Public Health, Security, and Law Enforcement Partnership in Bio-Incident Pre-Planning and Response and associated Southern Caucasus BioShield 2010 tabletop exercise; and the The Trilateral (US-Romania-Moldova) Civilian-Military Forum on Outbreak Response and Bioterrorism Investigation, respectively); these events aimed to strengthen the core capacities required by the WHO International Health Regulations and existing national measures consistent with obligations under the Biological Weapons Convention and the UN Security Council Resolution 1540 to deter, prevent, or respond to biological incidents or threats.	

Excerpts from the 1540 Matrix of the United States, updated on 30 December 2010

Full text online at: *http://www.un.org/sc/1540/approvedmatrices.shtml*

Other opportunities for reporting on national implementation of UNSCR 1540: domestic visits

U.S. DEPARTMENT OF STATE

DIPLOMACY IN ACTION

United Nations Security Council Resolution 1540 Committee Visit to Washington, DC

Media Note

Office of the Spokesperson

Washington, DC

September 8, 2011

The Committee established by United Nations Security Council Resolution 1540 (UNSCR 1540) and its Group of Experts will visit Washington, DC on September 12, 2011. The visit is coordinated by the U.S. Department of State. The United States will be one of the first countries to welcome the UN 1540 Committee to carry out a detailed fact-finding mission on how the United States implements UNSCR 1540 obligations. The United States hopes to help identify collaborative standards on implementing the resolution effectively, and hopes to encourage other nations to invite the UN 1540 Committee to visit their countries for similar fact-finding missions.

http://www.state.gov/r/pa/prs/ps/2011/09/171907.htm

Simon Limage, Deputy Assistant Secretary for Nonproliferation Programs , Bureau of International Security and Nonproliferation, U.S. Department of State, and **Ruvarna Naidoo**, Acting Spokesperson for the UNSCR 1540 Committee Chairman, Washington, DC, 15 Sep 2011, The Washington Foreign Press Center

http://fpc.state.gov/172523.htm

Briefing & tour of the NIH BSL-4 Training Facility, National Biosafety & Biocontainment Training Program

http://nbbtp.org

US International Assistance Relevant to Biosafety and Biosecurity

- Support to the **WHO, BWC ISU, and 1540 Committee**
- Support to *the* ***G8 Global Partnership Against the Weapons and Materials of Mass Destruction***
- Direct (one-on-one) assistance
- **Departments/Agencies -specific programs**

"… President Obama addressed the United Nations General Assembly and urged the global community to come together to prevent, detect, and fight every kind of biological danger, whether it is a pandemic, terrorist threat, or treatable disease.

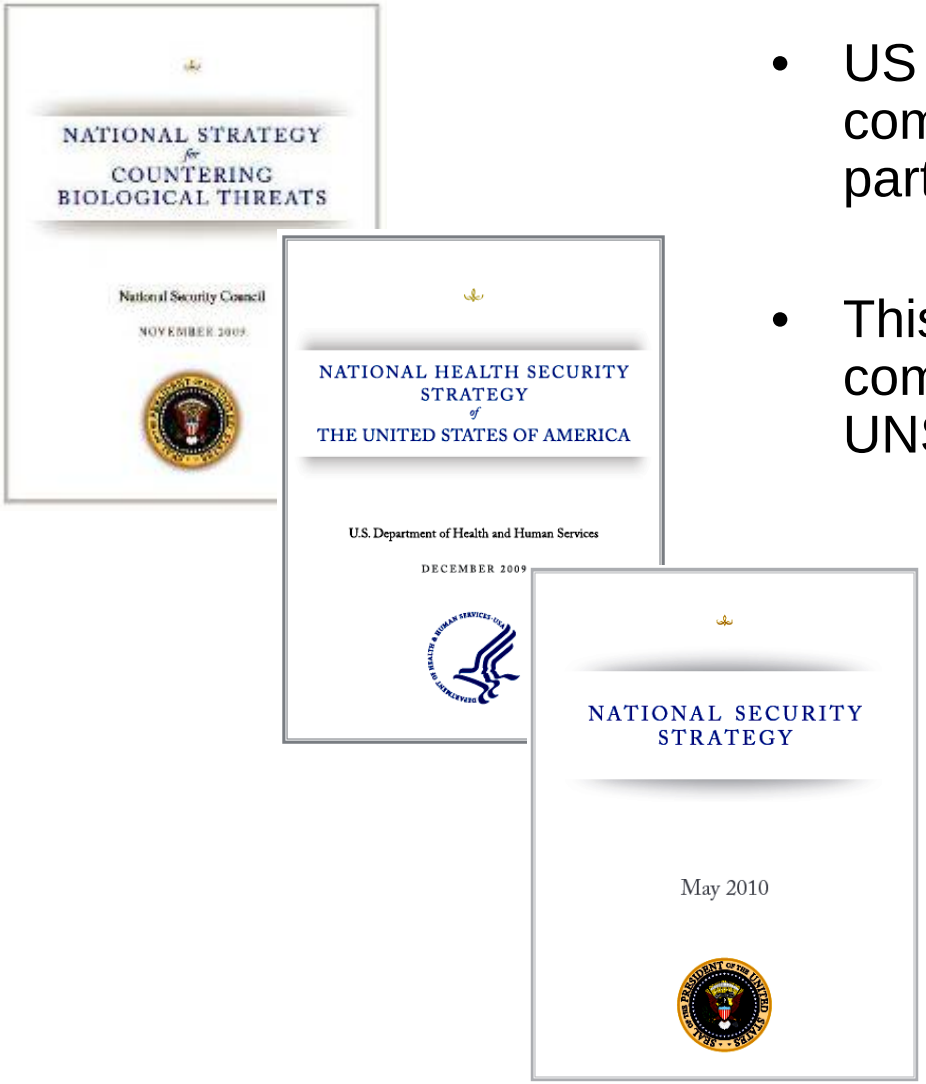
The United States is taking a multi-faceted approach to the full spectrum of challenges posed by infectious diseases, whether naturally occurring, accidental, or the result of a deliberate attack.

Through fora such as the UN Security Resolution 1540, the Biological Weapons Convention (BWC), and the World Health Organization (WHO), the United States is pursuing a common vision where disease no longer threatens the security and prosperity of nations".

White House Fact Sheet: Global Health Security, 22 Sep 2011

http://www.whitehouse.gov/the-press-office/2011/09/22/fact-sheet-global-health-security

US Commitment



- US Strategies emphasize the US commitment to work with international partners to advance global health security
- This strategic goal is also imprinted in the common tenets of WHO IHRs, BWC, and UNSCR 1540, aiming to:

Promote international dialogue and cooperation &

Strengthen national systems and frameworks of bio risk management,

To ensure and promote the peaceful, safe, & secure pursuit of life sciences for the benefit of all

United States Department of

Health & Human Services

Office of the Assistant Secretary for Preparedness and Response (ASPR)

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