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

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

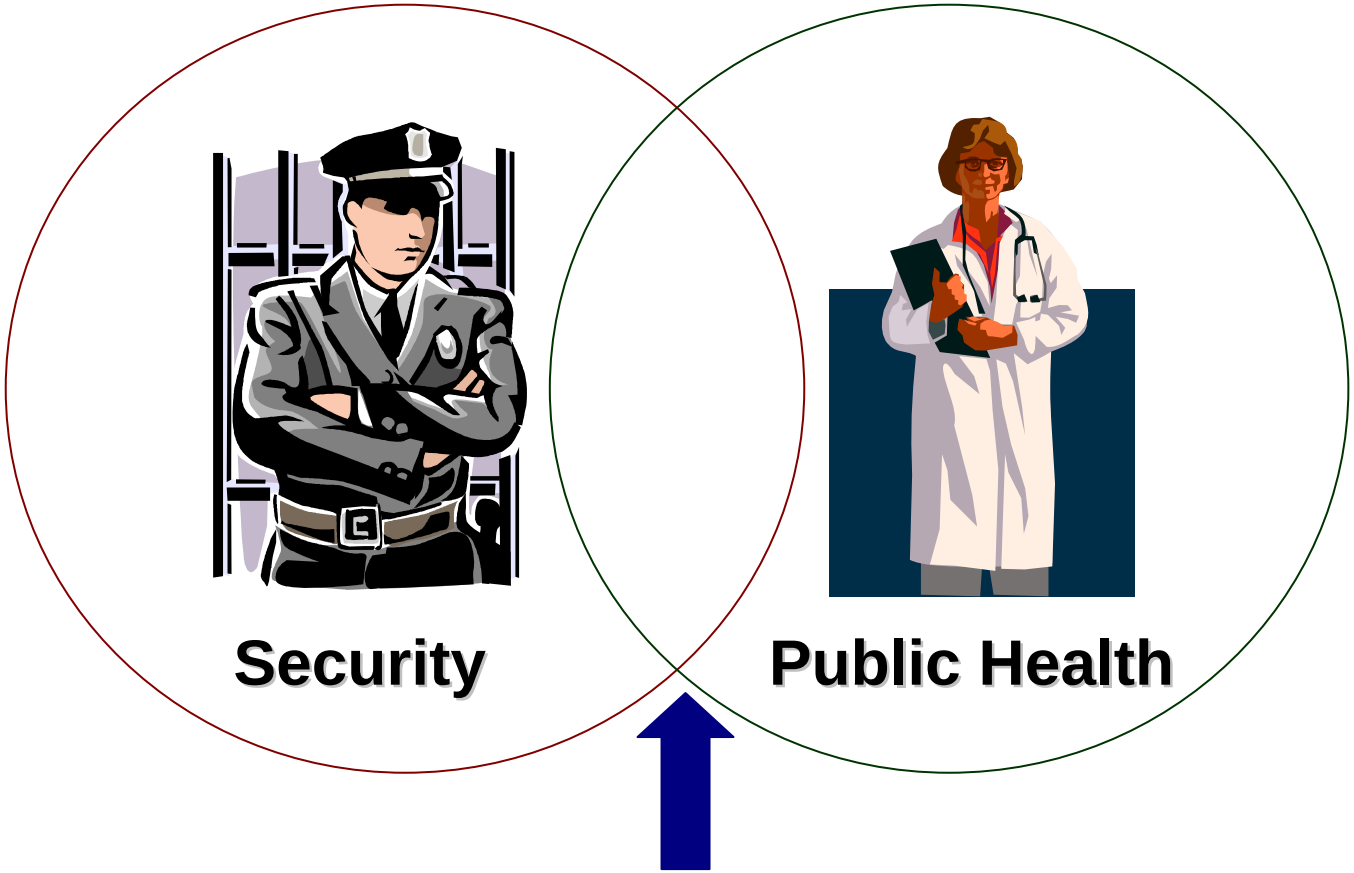
*Maximize the Use of Limited Resources:*
*Overview and Practical Tips on Compliance*

**Dana Perkins, PhD**

Countering Biological Threats:
National Implementation of the Biological Weapons Convention and Multinational Outbreak Response and Bioterrorism Investigation Demonstration,
17-19 May 2011, Tbilisi, Georgia

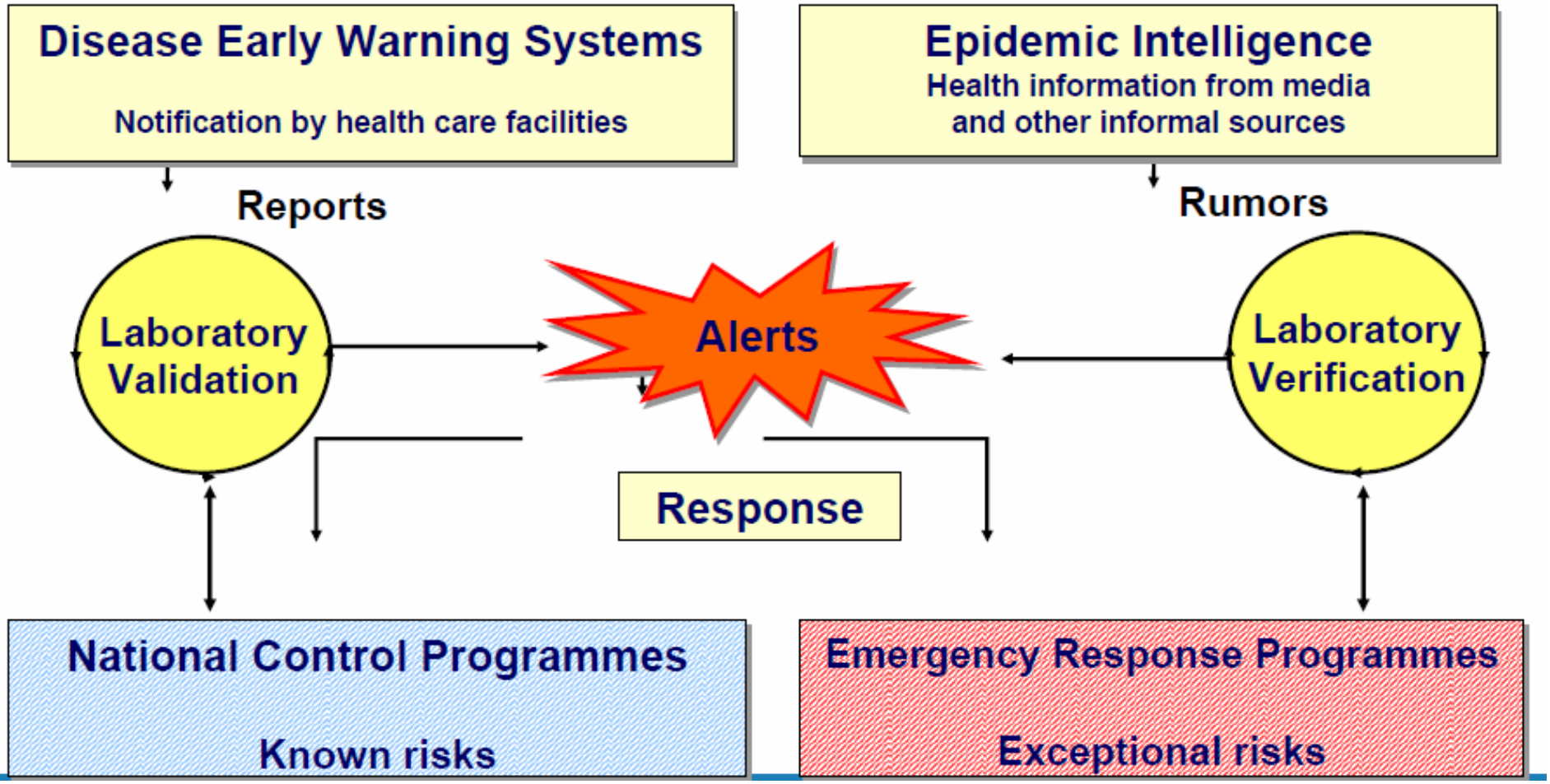
# Disclaimer

*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.*



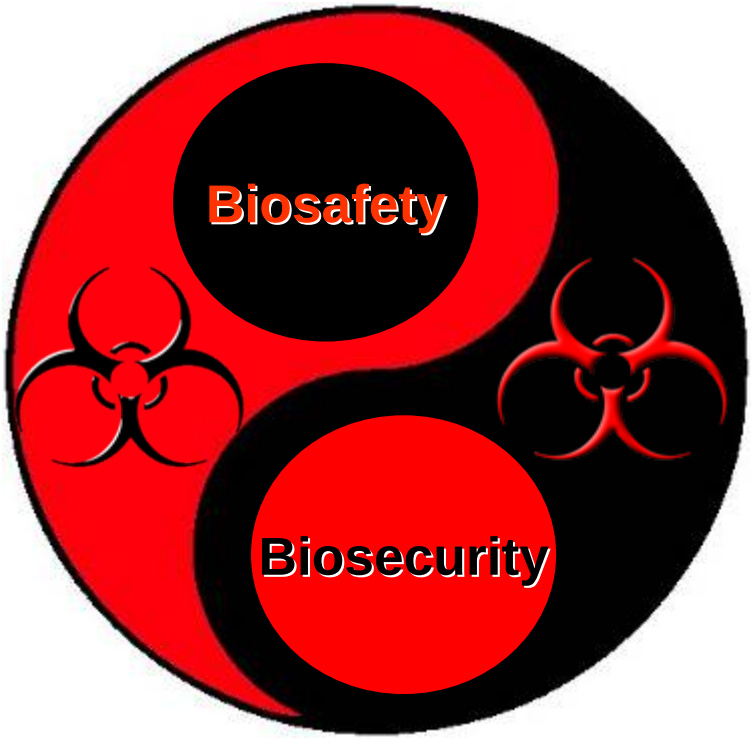

***Health Security***

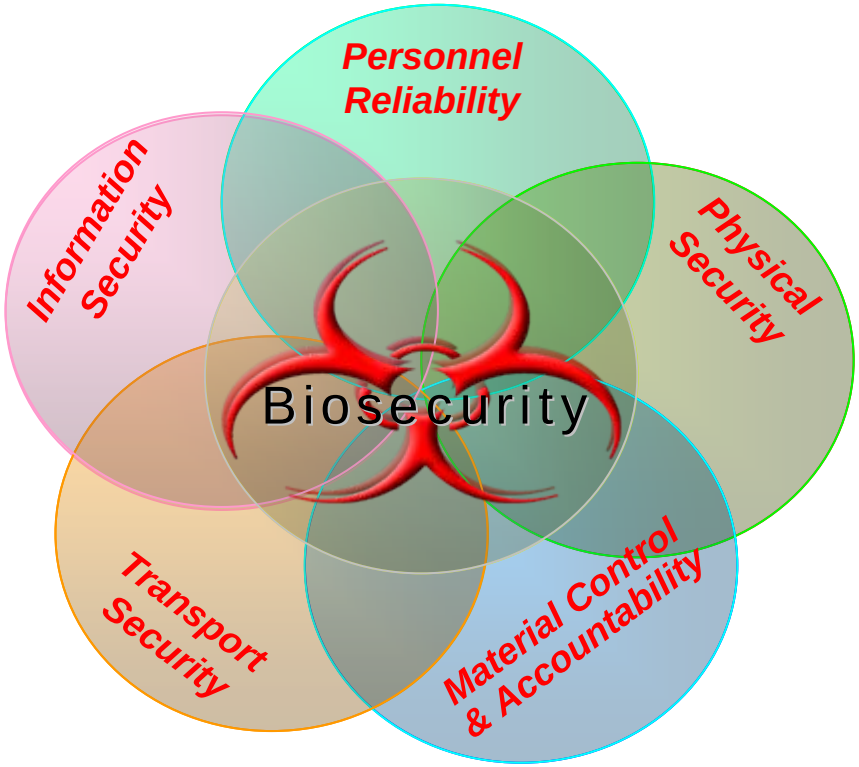
# Lab Capacities & Health Security




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

# Biological Risk Management



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

| | WHO IHRs (2005) | BWC | UNSCR 1540 |
|---|---|---|---|
| **Applicability:** | **All 194 WHO States Parties** | **163 BWC States Parties** | **All 192 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****<br>**** 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.

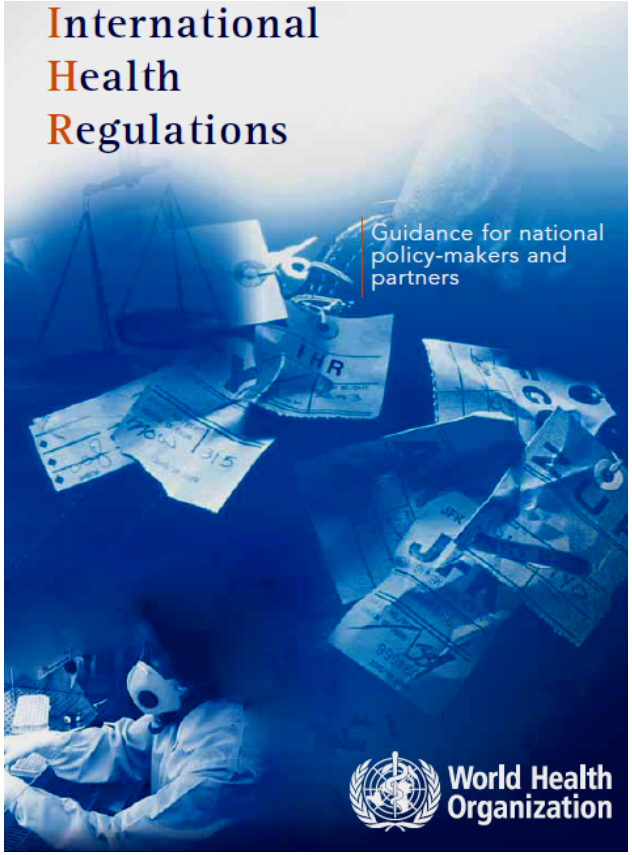
- Each State Party to the IHR(2005) therefore contributes to a global legal framework for the detection of and response to international public health risks and potential public health emergencies of international concern.

- 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

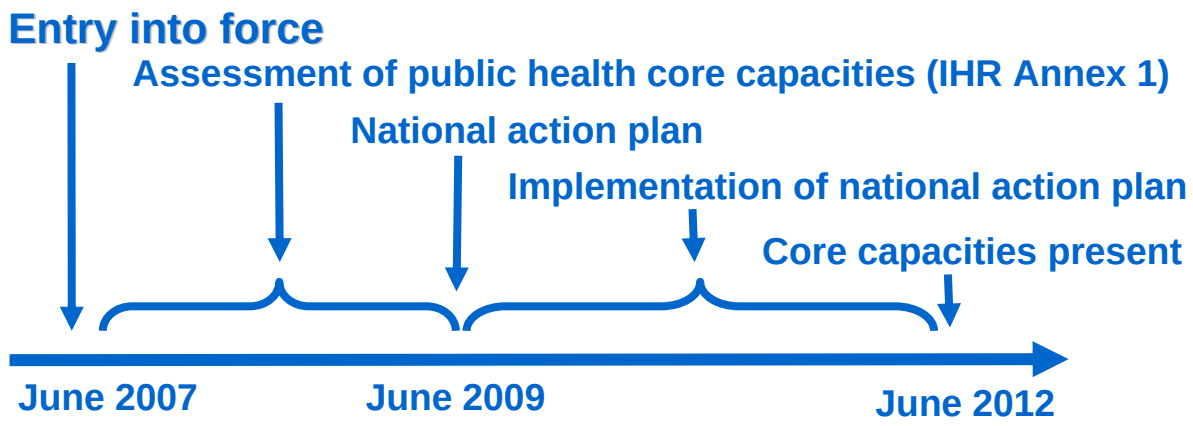
# Requirements of the International Health Regulations

***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

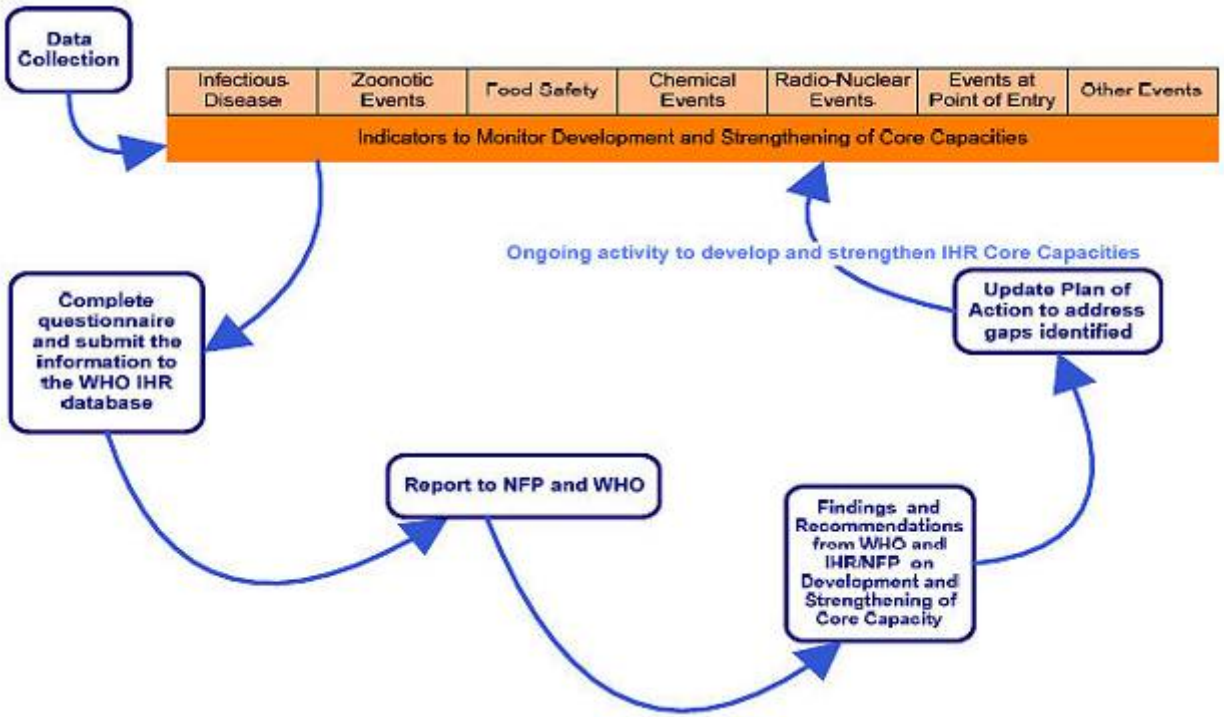


# Laboratories & the IHRs

*"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.<br><br>National reference laboratory(ies) (NRL) designated and list of NRL disseminated to relevant stakeholders.<br><br>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].<br><br>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).<br><br>Greater than 10 non-AFP hazardous specimens per year referred to **national** or international reference laboratories for examination.<br><br>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.<br><br>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.<br><br>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?

# Knowledge Check

## Is the legislation on biosafety/biosecurity, IHR-related and / or reportable?

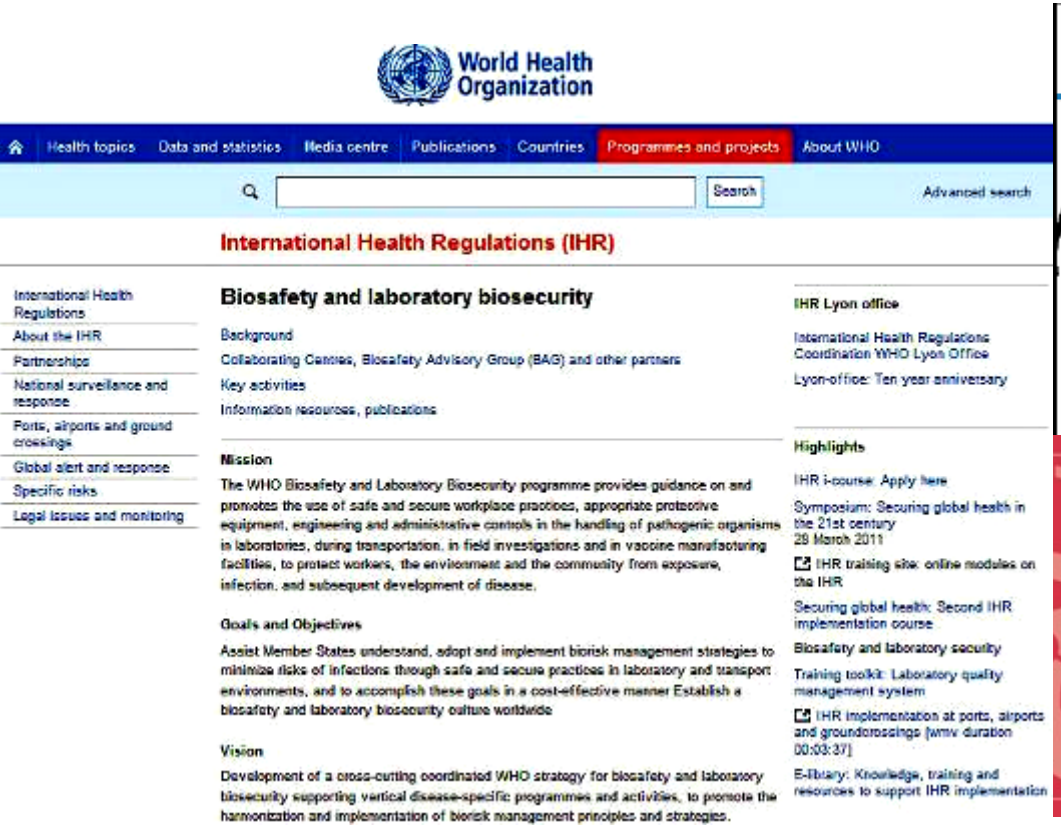
a. Such legislation has nothing to do with the IHRs

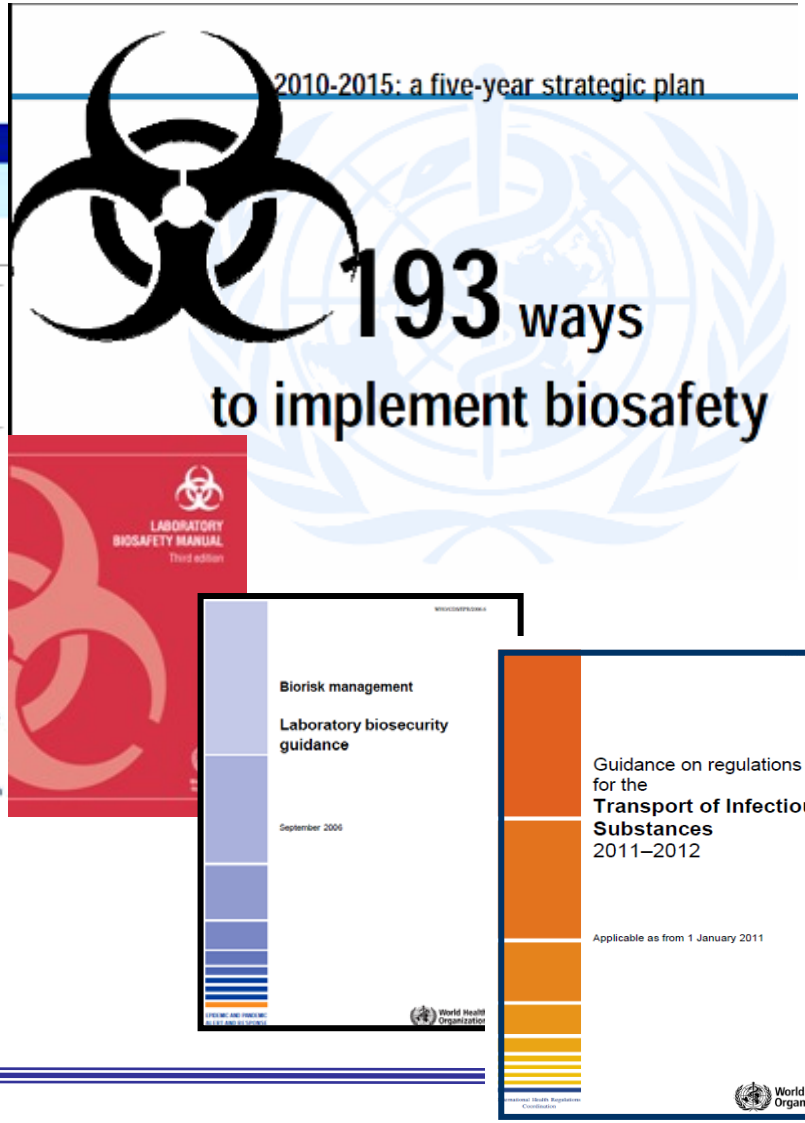
b. Yes, it is related and it is captured under the National legislation & policy component of Core Capacity 1

c. Yes, it is related but we don't need to worry about reporting it

| Core Capacity 1: National [14] legislation, policy & financing | | | | | |
|---|---|---|---|---|---|
| Component | Country level indicator | Status of development of IHR core capacities by capability level | | | |
| | | <1 Prerequisites | 1 Inputs and processes | 2 Outputs and outcomes | 3 Additional achievements |
| National legislation and policy | Laws, regulations, administrative requirements[15], policies or other government instruments in place are sufficient[16] for implementation of obligations under the IHR. | Not Applicable [17] | Assessment[18] of relevant legislation, regulations, administrative requirements and other government instruments for IHR (2005) implementation has been carried out, with a report available. | Documentation that the country recommendations following assessment of relevant legislation, regulations, administrative requirements and other government instruments are implemented is available. | A compilation of national IHR-related legislation, is published [19]. |
| | | | Review of national policies to facilitate the implementation of IHR NFP functions and technical core capacities[20]. | Documentation that policies to facilitate IHR NFP core and expanded[21] functions and | |

# WHO Resources for Technical Assistance on Biosafety / Biosecurity




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

# IHRs implementation: "it takes a village"

**Example of WHO key partners to support IHR implementation**

- Other intergovernmental organizations

  **UN system** (e.g. Food and Agriculture Organization (FAO), International Atomic Energy Agency (IAEA), International Civil Aviation Organization (ICAO), International Labour Organization (ILO), International Maritime Organization (IMO), United Nations Children's Fund (UNICEF), World Trade Organization (WTO));
  **regional** (e.g. Association of Southeast Asian Nations (ASEAN), European Union (EU), Mercado Común del Sur (Mercosur));
  **technical** (e.g. World Organization for Animal Health (OIE)).

- **International aid agencies** (e.g. Asian Development Bank (ADB), Agence française de développement (AFD), Canadian International Development Agency (CIDA), UK Department for International Development (DFID), Japan International Cooperation Agency (JICA), The Netherlands, Swedish International Development Cooperation Agency (Sida), United States Agency for International Development (USAID), World Bank).

- **WHO Collaborating Centres / networks of excellence** (e.g. Global Outbreak Alert and Response Network (GOARN), Institut Pasteur, United States Centers for Disease Control and Prevention (CDC)).

- **Academics and professional associations** (e.g. International Association of National Public health Institutes (IANPHI), American Public Health Association (APHA)).

- **Industry associations** (e.g. Airports Council International (ACI), International Air Transport Association (IATA), International Shipping Federation (ISF), Union of International Railways (UIR)).

- **Nongovernmental organizations** (NGOs) and **foundations** (e.g. The GAVI Alliance, International Federation of Red Cross and Red Crescent Societies (IFRC), International Committee of the Red Cross (ICRC), Médecins sans frontières (MSF)).

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

| | WHO IHRs (2005) | BWC | UNSCR 1540 |
|---|---|---|---|
| **Applicability:** | **All 194 WHO States Parties** | **163 BWC States Parties** | **All 192 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****<br>**** CBM voluntary reporting / BWC ISU / every year by 15 April*** | Status of implementation / 1540 Committee / *"without delay"* |

# 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/unog/website/disarmament.nsf/(httpPages)/FD59A71FC0B3FAF8C12574780052F81A?OpenDocument***

# BWC Confidence Building Measures (CBMs)

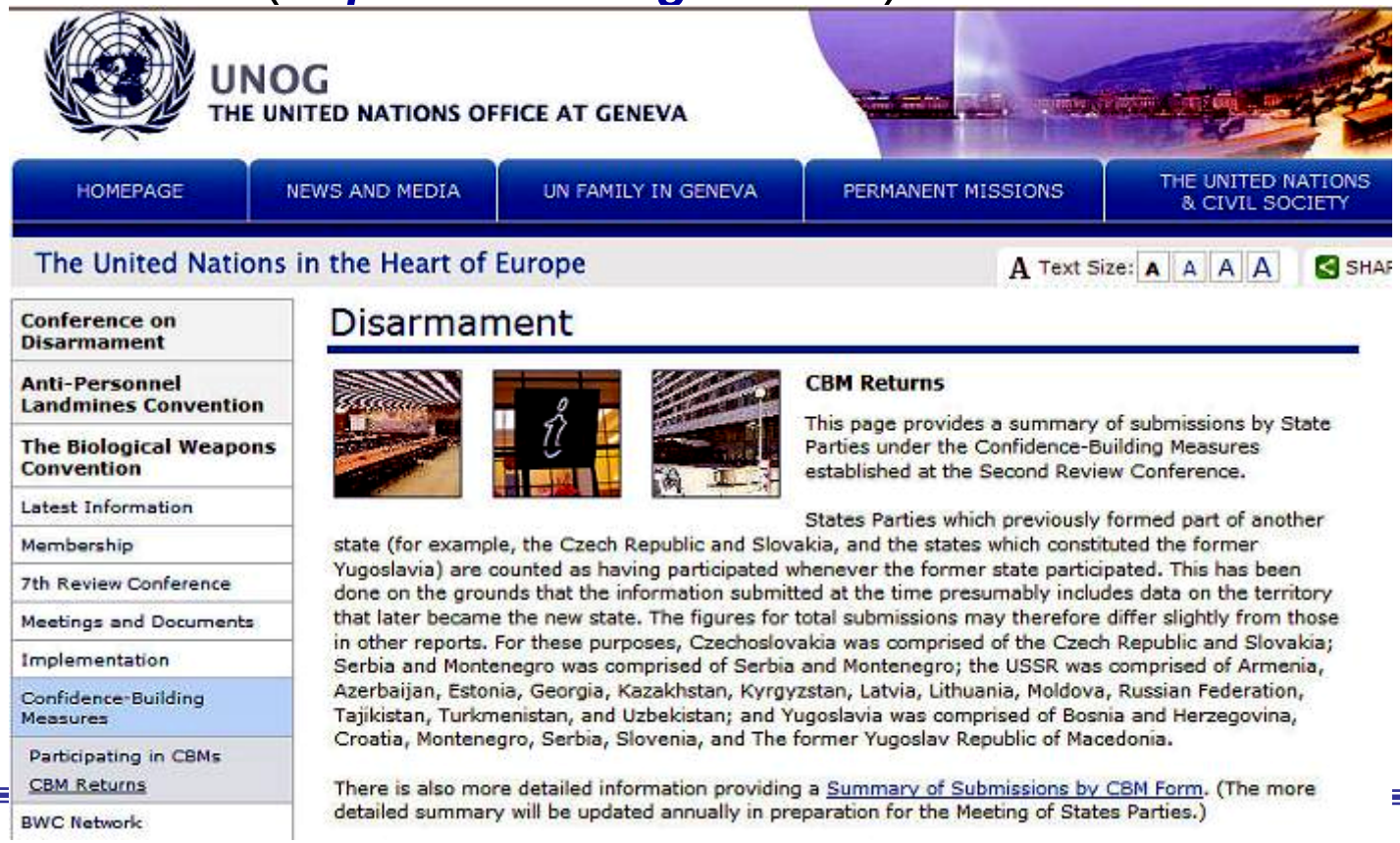
- 1986 agreement: introduce CBMs ***"in order to prevent or reduce the occurrence of ambiguities, doubts and suspicions and in order to improve international cooperation in the field of peaceful biological activities"***
- CBMs were elaborated in 1987 and modified/expanded in 1991; submission / distribution 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".

**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

**Confidence-Building Measures**

- 2009 CBM Return

**OPP Divisions**

- Division for At-Risk,

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

the WHITE HOUSE PRESIDENT BARACK OBAMA

Get Email Updates | Contact Us

BLOG | PHOTOS & VIDEO | BRIEFING ROOM | ISSUES | the ADMINISTRATION | the WHITE HOUSE | our GOVERNMENT

Home • The Administration • Office of Science and Technology Policy

Search OSTP | Search

# Office of Science and Technology Policy

About OSTP | OSTP Blog | Pressroom | Divisions | R&D Budgets | Resource Library | NSTC | PCAST | Contact Us

**NSTC**

- About NSTC
- Committees
- Meetings
- Documents & Reports
- Topics
  - Aeronautics Science & Technology
  - Biosecurity
  - Ocean Science & Technology
  - NNI Strategy

## Biosecurity

This website was established to inform the public and the academic and private sector research communities about government policies related to the safe and secure conduct of biological research and the technologies arising out of the application of the life sciences. Created by the Office of Science and Technology Policy within the Executive Office of the President, this website will:

- host the most updated and factual information regarding biosecurity policy as it is being initiated, developed and promulgated by the U.S. Government;
- provide answers to frequently asked questions
- provide advisory materials and reports from which recommended policies may be based: and
- provide a calendar for public meetings and opportunities for public input

**Website hosted by OSTP, Executive Office of the President:**

***http://www.whitehouse.gov/administration/eop/ostp/nstc/biosecurity***

# Opportunities to Report on Biosafety / Biosecurity in CBMs

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

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 -

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

**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

Submitted to the United Nations on
April 15, 2011

**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

# 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

**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 |

**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.

**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 **Seventh 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 Sixth 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
  - Collaboration and assistance

***Tip for future reporting: 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*

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

| | WHO IHRs (2005) | BWC | UNSCR 1540 |
|---|---|---|---|
| **Applicability:** | **All 194 WHO States Parties** | **163 BWC States Parties** | **All 192 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****<br>**** 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 ;**l 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

Home
New on this website NEW
Resolutions and Presidential Statements
Committee and its Work
Reports and other Submissions to the Security Council
National Implementation of Resolution 1540
- Guidelines for Reporting by States
- National Reports
- Other National Documents
- The 1540 Matrix

Legislative Database
Assistance
Outreach
FAQ
Media

## 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<br>7 September 2005<br>30 April 2008 | S/AC.44/2004/(02)/73<br>Add.1<br>S/AC.44/2007/1 |
| Andorra | 27 October 2004<br>31 October 2005<br>13 March 2008 | S/AC.44/2004/(02)/19<br>Add.1<br>Add.2 |

Home

New on this website NEW

Resolutions and Presidential Statements

Committee and its Work

Reports and other Submissions to the Security Council

National Implementation of Resolution 1540

- Guidelines for Reporting by States
- National Reports
- Other National Documents
- The 1540 Matrix

Legislative Database

Assistance

Outreach

FAQ


## 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***

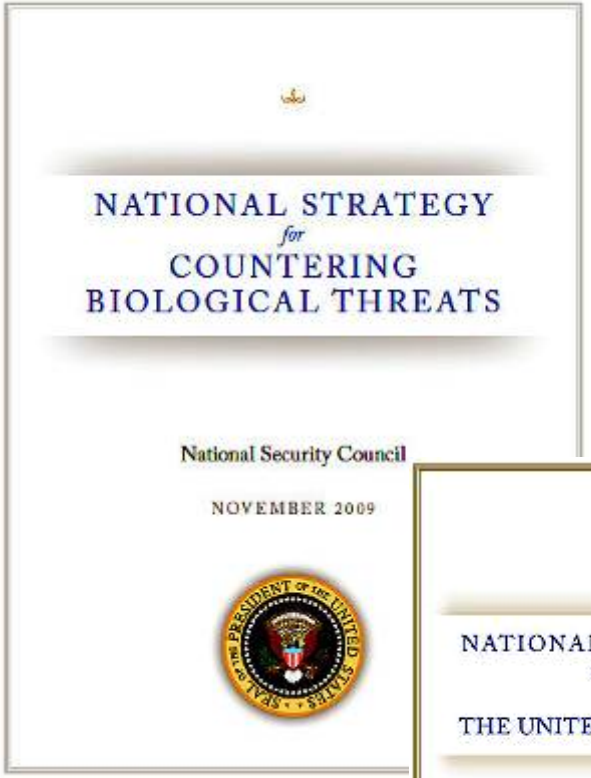
**Full text online at: *http://www.un.org/sc/1540/approvedmatrices.shtml***

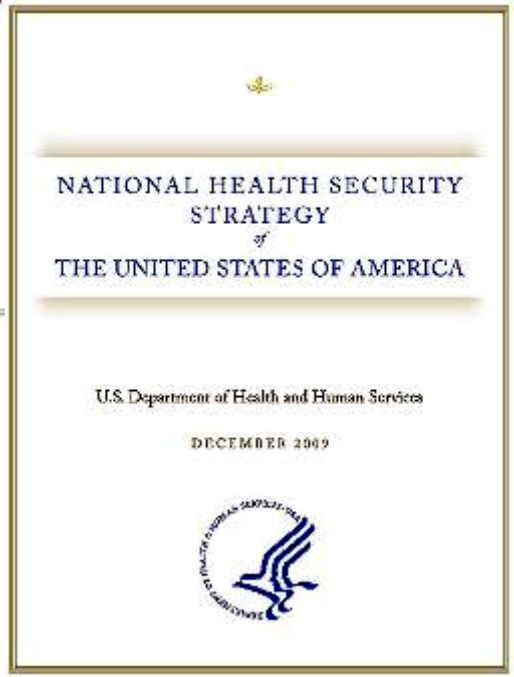
# US International Assistance Relevant to Biosafety and Biosecurity

- 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**

***…"we also declare our intent to give new impetus to implementation of U.N. Security Council Resolution 1540 on preventing non-state actors from obtaining WMD-related materials and technologies"- President Obama, 01 April 2009***

# 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 WHO IHRs, BWC, and UNSCR 1540 common tenets to:
  - Promote international dialogue and cooperation and to
  - Strengthen national systems and frameworks of biological risk management, to
  - Ensure and promote the peaceful, safe and secure pursuit of life sciences for the benefit of humanity

United States Department of

Health & Human Services

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

# Contact information:

## Dana Perkins, Ph.D.

*Chief, BW Nonproliferation and Counterterrorism Branch*
*Division of Biosafety, Biosecurity & Countering Bio Threats*
*Office of Policy & Planning*
*Office of the Assistant Secretary for Preparedness & Response, U.S. Department of Health and Human Services*
*Tel: (202) 205 5716 (office)*
*E-mail: dana.perkins@hhs.gov*