

# SAFETY and GLOBAL PUBLIC HEALTH: How do the International Health Regulations partner up with country needs?

A Perspective from the World Health Organization

**African Biological Safety Association (AfBSA)**

**March 9-13, 2009**

**Nairobi, Kenya**

**Presented by May C. Chu, Ph.D**



**World Health  
Organization**

# Health Security and Environment

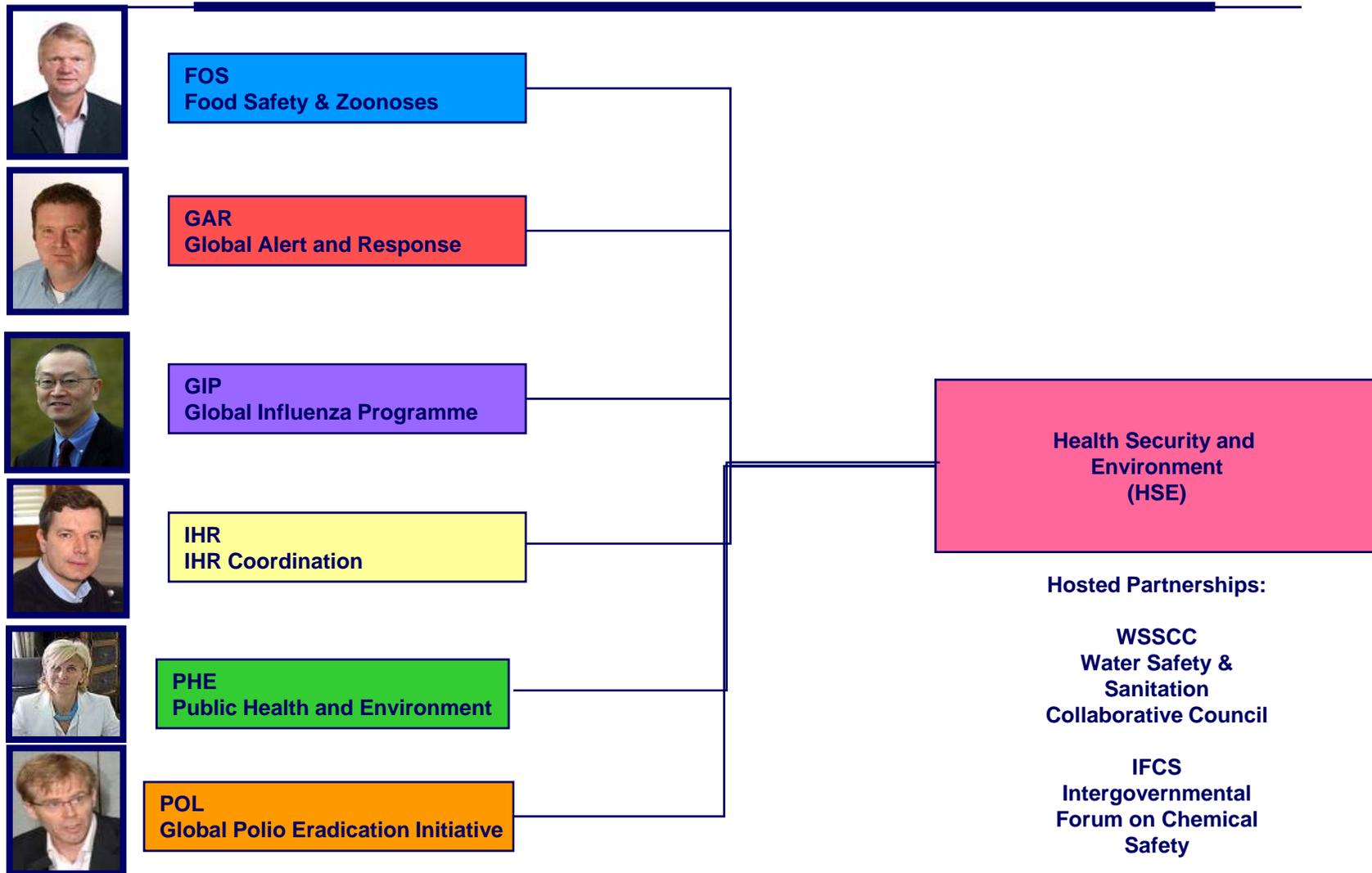
Formerly the Communicable Diseases and Surveillance cluster

## HSE combines under one cluster:

- Global Alert and Response
- Food Safety
- Public Health Environment
- International Health Regulations
- Global Influenza Programme
- Polio Eradication Programme

Brings together “all-hazards”, “all-hands” operational concept

# Proposed Structure HSE Cluster: Departments, 5 September 2008



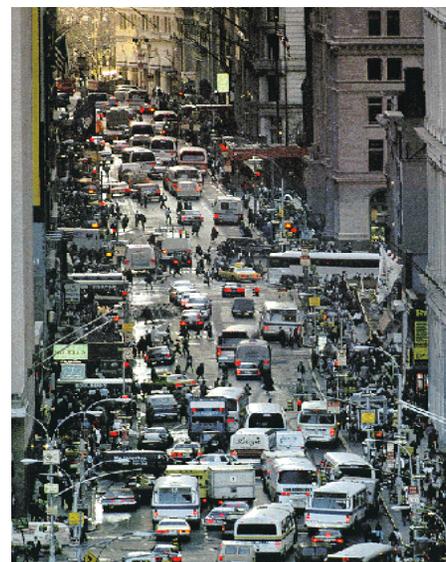
# Discussion themes

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- International Health Regulations: the background and argument for investing in capacity building
- Resources: publications, workshops and capacity building partnerships
- Approaches for integrating services and resources to meet the requirements for implementation of the IHR at country level

# A Changing World

- **Population growth**
- **Population ageing**
- **Population movements**
- **Urbanization**
  
- **Biotechnologies**
- **Food processing**
- **Globalized trade**
- **Access to remote biotopes**
- **Industrial pollution**
- **Climate change**
- ...



# Events that Impact International Public Health Security ...



HIV/AIDS



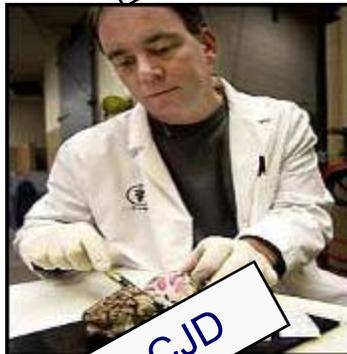
Chernobyl



Plague



Ebola / Marburg



NvCJD



Nipah



Anthrax



SARS



meningitis



cholera



Chemical spill



Avian Influenza

Health Security and Environment

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# The Global Responsibility

The WHO World Health Report 2007:  
Global Public Health in the 21<sup>st</sup> Century

THE WORLD HEALTH REPORT 2007

# A SAFER FUTURE

GLOBAL PUBLIC HEALTH SECURITY IN THE 21ST CENTURY

**Epidemic-prone diseases**

**Foodborne diseases**

**Accidental and deliberate outbreaks**

*biological, toxic chemical, radionuclear and environmental  
disasters*



World Health  
Organization

# Laboratory Accidents and Bio-Risks

Selected examples of laboratory acquired  
infections:

SARS: Singapore, 2003

SARS: Taiwan, 2003

SARS: China, 2004

Tularemia: USA, 2004

Ebola: Russia, 2004

Potential exposure (high consequence)

Anthrax: Soviet Union, 1979; USA, 2001

H2N2: USA and Canada, 2005

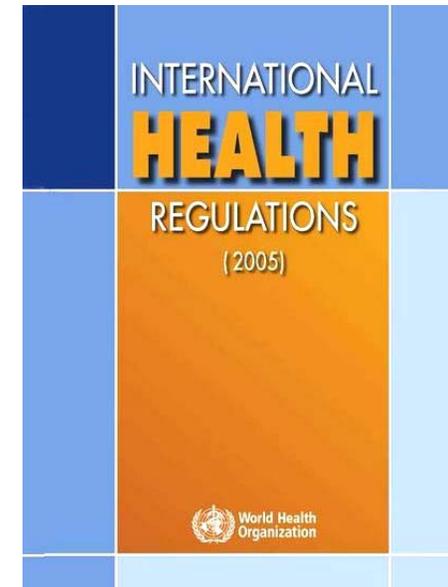


# International Health Regulations 2005

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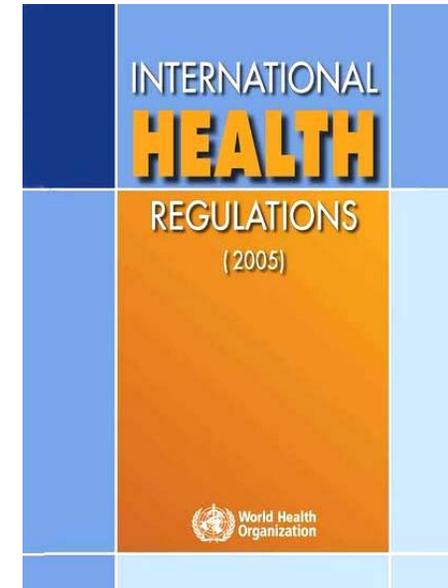
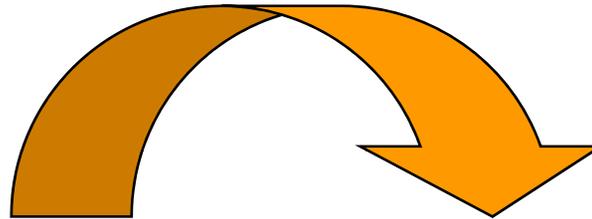
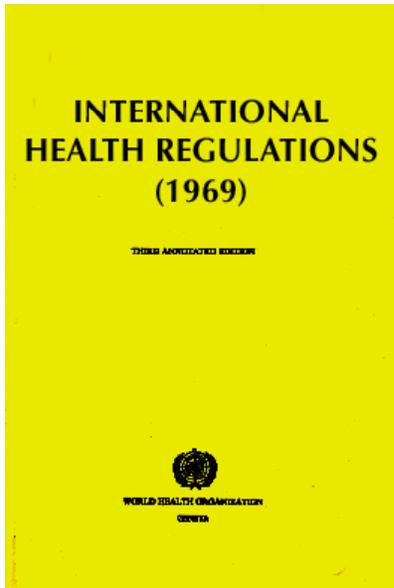
## Article 2:

Prevent, protect against, control and provide a public health response to the international spread of disease commensurate with public health risks, and which avoid unnecessary interference with international traffic and trade



# International Health Regulations 2005

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From three diseases to all public health events

From passive to pro-active using real time surveillance/evidence

From control at borders to detection and containment at source

# WHO: vision for revision of the International Health Regulations, 1996

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- *A world on the alert and able to detect and respond to international infectious disease threats within 24 hours using the most up to date means of global communication and collaboration*
- *A change in the norms surrounding reporting of infectious disease outbreaks, making it expected and respected to report*

# State Party and WHO responsibilities

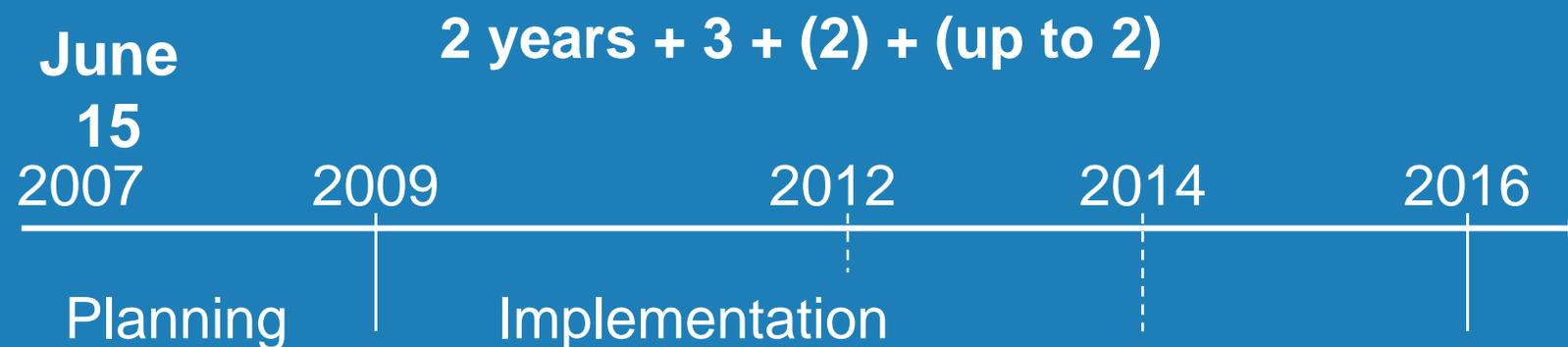
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**State Party (194 countries)** shall develop the capacity to detect, assess, notify and report events in accordance with these Regulations, as specified in Annex 1 and assess events in their territory according to the decision instrument (Annex 2)

**WHO** shall assist States Parties, upon request, to develop strengthen and maintain these capacities (art. 5)

IMPLEMENTATION OF THE IHR  
STRENGTHEN NATIONAL CAPACITY  
(194 Member States)

• Timeline

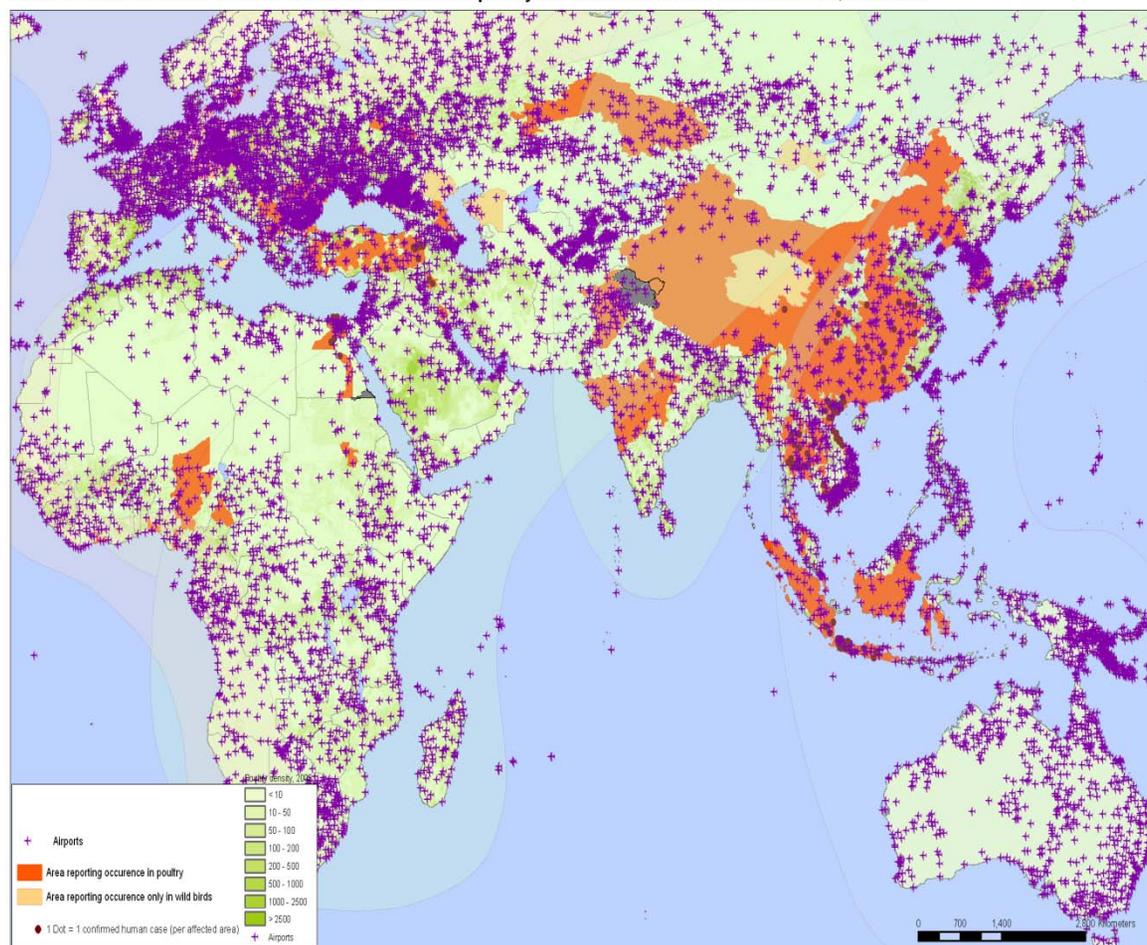


"As soon as possible but no later than five years from entry into force ..."  
(Articles 5, 13)

# Supporting early detection and response to epidemics: avian influenza



Avian Influenza : confirmed human cases and occurrence in poultry and wild birds of H5N1 avian influenza, since 2003



## Airports

AN EXAMPLE OF CHALLENGE TO CERTIFY COMPLIANCE TO IHR AT THE PORTS OF ENTRY, including safety, disease-free and vector-free

 The boundaries and names shown and the designations used on this map do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted lines on maps represent approximate border lines for which there may not yet be full agreement. Communicable Diseases (CDS) World Health Organization © WHO 2006. All rights reserved

Data source: World Organisation for Animal Health (OIE) and national governments/WHO/EPR  
Map Production: Public Health Mapping and GIS

# Challenges from the IHR(2005)

Large flexibility between domestically and outsourced capacity

No clear instructions on laboratory requirements:

- At what level should testing take place (peripheral, central, supranational)?
- Any requirement for sample collection and transportation?
- Any minimal level of quality assurance?
- When lab data should be available (within the 48h+24h period of assessment and notification?)

A strict interpretation of the text would mean that the laboratory capacity could be fully outsourced

# 194 Flavors

Utilize and build on existing infrastructure

Trust and confidence in the data received from countries: quality assurance framework

Ensure that the strategies and requirements of the different vertical programmes fit into IHR(2005) requirements

Support the countries in their cross-sectoral assessment (by 2009) and capacity building (by 2012) process:

- self assessment (checklists) and assessment missions
- proactive assessment (IHR laboratory exercise as measurement of functional capacity to respond to Annex II and for making a country's plan)
- Support to national planning effort

# What is a PHEIC?

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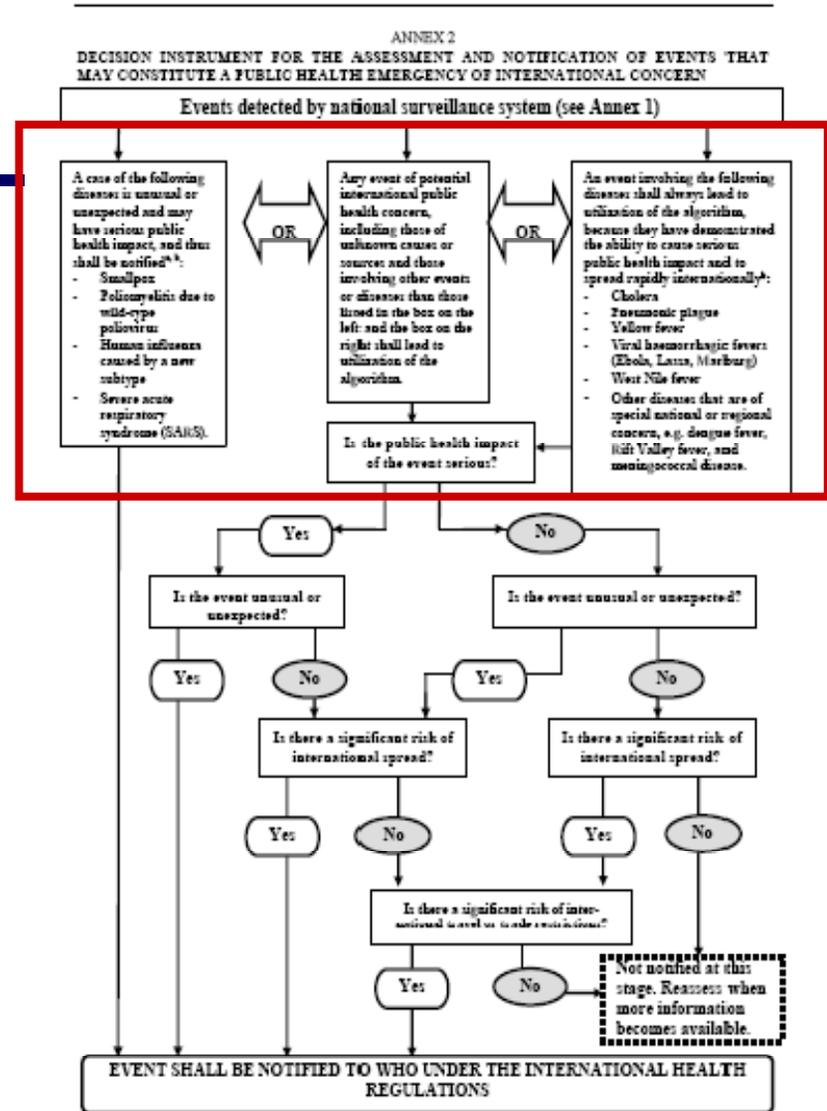
WHO shall collect and analyze information regarding to events and determine its potential to cause *public health emergency of international concern*, irrespective of origin or source and may share information with intergovernmental organizations following verification procedure with the affected State Party (articles 5, 6, 7, 10, 11, 12, 13, 14; Annex 1,2)

# IHR 2005, Annex 2

## A decision instrument to identify an event that may spread internationally

3 situations are to be considered:

- any single case will require reporting
- any one of these diseases known to have ability to spread
- any event of serious impact that may spread



<sup>a</sup> As per WHO case definitions.

<sup>b</sup> The disease list shall be used only for the purposes of these Regulations.

Once notified, countries have 48 hours to investigate and 24 hours to make report of investigation to WHO

# Annex 2-The Decision Instrument

## 4 questions

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- Is the public health impact of the event serious?
- Is the event unusual or unexpected?
- Is there a significant risk of international spread?
- Is there a significant risk of international travel or trade restrictions?

**IF "YES" TO 2 OF 4 QUESTIONS, THE STATE PARTY SHOULD NOTIFY WHO OF THE EVENT under Article 6**

# Resources

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Advisory Groups

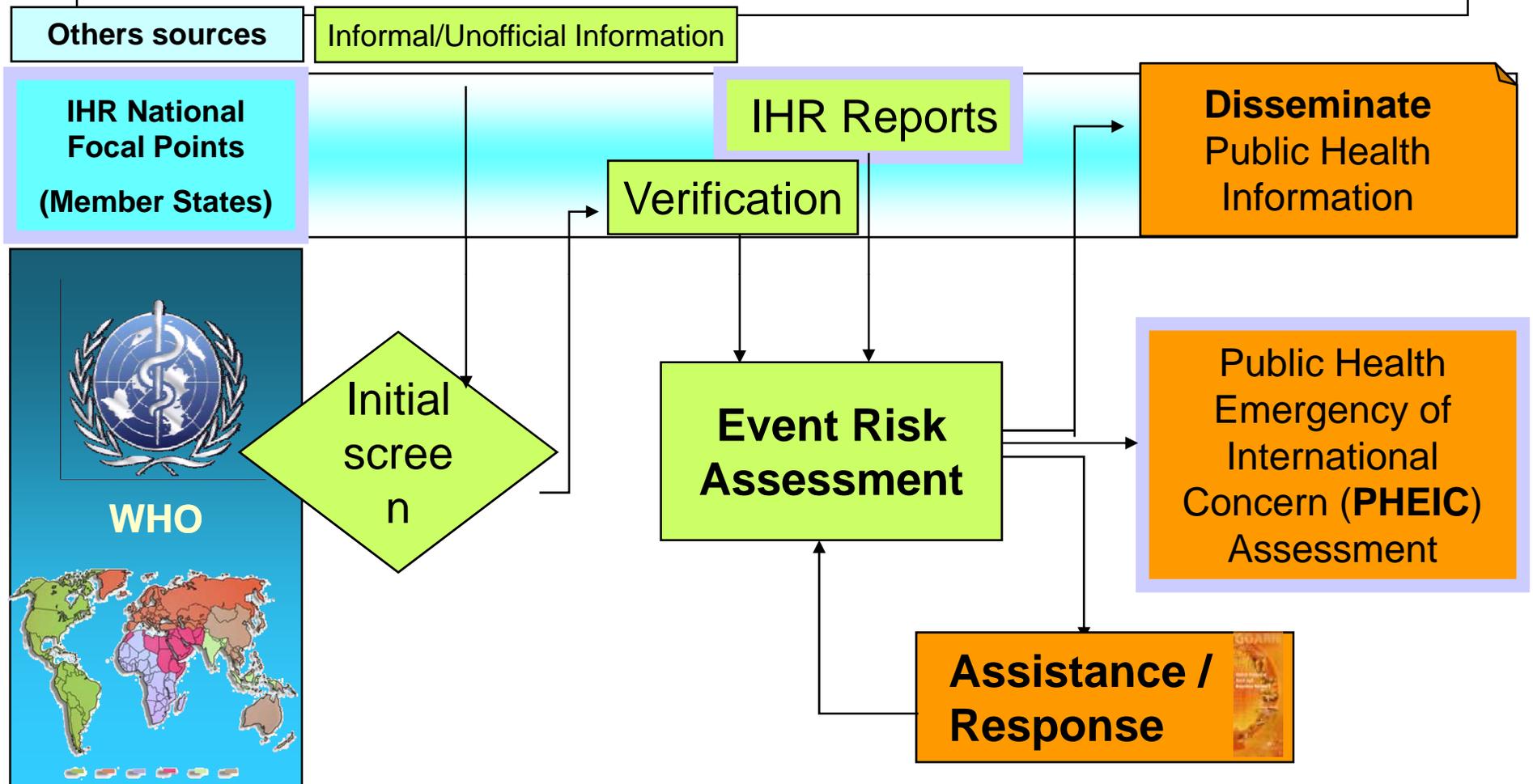
Publications

Guidelines

Tools

Training Workshops

# Risk/Event Management Process



# Global alert: Rift Valley Fever, Sudan, 7 November

The screenshot shows the WHO Event Information Site interface. At the top, there are language options: عربي, 中文, English, Français, Русский, and Español. The site title is 'Event Information Site for IHR National Focal Points'. A search bar and a 'Welcome Tom Grein [Logout]' message are visible. The main content area is titled 'Sudan/Rift Valley Fever' and includes a 'Product' section with checkboxes for 'Serious Public Health Impact', 'International disease spread', 'Unusual or Unexpected', and 'Interference with international travel or trade'. The 'Risk Assessment Comments' section describes the high case fatality rate and potential for epidemic spread. The 'Verification Status' is 'WHO-NFP risk assessment ongoing'. The 'IHR Status' is 'Public Health Risk (PHR)'. The 'Laboratory Confirmed' checkbox is checked. The 'WHO IHR Contact Point' information is provided, including the AMRO/PAHO contact details. The 'Attachments' section is 'Not Available'. An 'Event update 2007-11-07 | Part 2' is highlighted, with a 'Withdraw Bulletin' button. The 'Event Bulletins' section on the right shows two updates from 2007/11/07. The 'Event History' section states 'There have been no updates for this event.'

# Event management system of the International Health Regulations

## States Parties

**Event Information Site**  
for IHR National Focal Points

**Current Events**

This site has been developed by WHO to facilitate secure communications with the IHR National Focal Points (NFP) part of the implementation of the International Health Regulations (2005). Information on this site is provided by WHO to National Focal Points, in confidence, as specified in Article 11.1.1 of the (2005).

**Current Events**

This section lists ongoing events which are currently being assessed against the criteria for public health risk international importance under the IHR (2005). Click an event's **Updated** link to see the current risk assessment and most recent updates for the event.

Updated	Country	Hazard	Syndrome	Disease	Initial Information On	IHR Status
2007/11/07	Peru	Product		Adverse effects of viral vaccines	2007/10/16	Public Health Risk (PHR)
2007/11/07	New Zealand	Product	Acute Neurological Syndrome, unsp...	Organic solvents, other, toxic effe...	2007/11/06	Public Health Risk (PHR)
2007/11/07	Australia	Product	Acute Neurological Syndrome, unsp...	Organic solvents, other, toxic effe...	2007/11/06	Public Health Risk (PHR)
2007/10/30	Sudan	Infectious	Acute Haemorrhagic Fever Syndrome	Rift Valley Fever	2007/10/17	Public Health Risk (PHR)

## Operations

**GOARN**  
Global Outbreak Alert and Response Network

**Current Events**

Weekly Outbreak Verification List Events (03<sup>rd</sup> March 2007)

**Current Events**

Event Name	Country	Event Date	IHR Status
Measles Outbreak - Kazakhstan	Kazakhstan	2007/02/27	Verified
Measles Outbreak - Mexico	Mexico	2007/02/27	Verified
Measles Outbreak - Kazakhstan	Kazakhstan	2007/02/27	Verified
Measles Outbreak - Kazakhstan	Kazakhstan	2007/02/27	Verified
Measles Outbreak - Kazakhstan	Kazakhstan	2007/02/27	Verified
Measles Outbreak - Kazakhstan	Kazakhstan	2007/02/27	Verified
Measles Outbreak - Kazakhstan	Kazakhstan	2007/02/27	Verified
Measles Outbreak - Kazakhstan	Kazakhstan	2007/02/27	Verified
Measles Outbreak - Kazakhstan	Kazakhstan	2007/02/27	Verified
Measles Outbreak - Kazakhstan	Kazakhstan	2007/02/27	Verified

**Event Management System**

## WHO Portal

HOME | CURRENT AGENDA & DAILY LIST | OPERATIONS | EMS | PUBLICATIONS | MEETING ARCHIVES | ABOUT

**Morning meeting site**

This site is developed in order to support information dissemination about events of potential international concern. The primary purpose of this site is to support the 09:00 hours Morning Meeting. This meeting is the central coordination mechanism and decision-making forum regarding the management of acute public health emergencies for WHO Alert and Response Operations... [READ MORE](#)

**Announcements**

Title	Created
PDF files refresh	24/04/2007 14:55

**In the last 24 hours...**

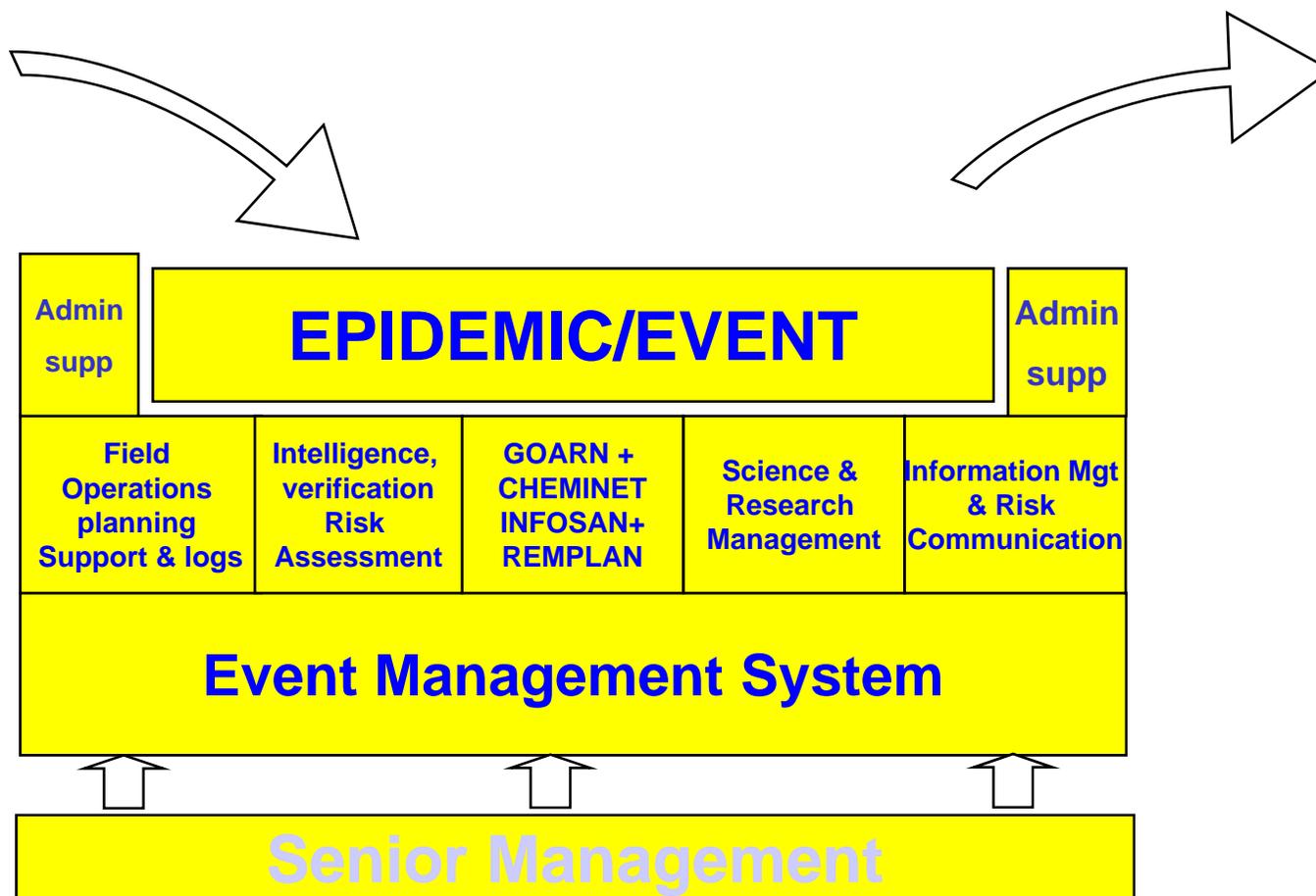
Type	Name	Document type	Document date
	Agenda 20071111	Daily agenda	13/11/2007
	20071112daily List	Daily list	12/11/2007

# Public Health Event Response under the International Health Regulations

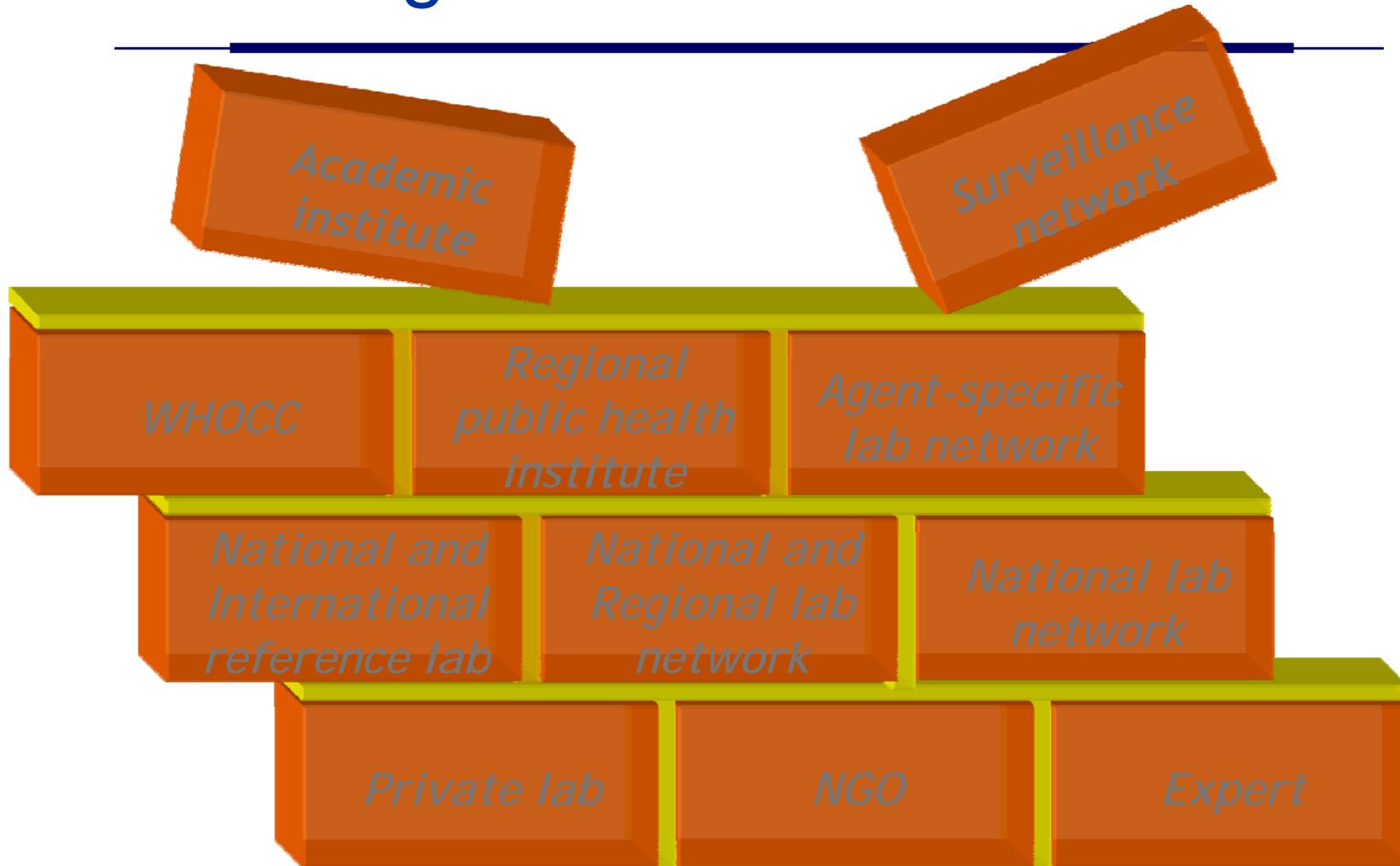
Specialist Programmes

- CHEMICAL
- RADIATION
- FOOD
- EPIDEMIC

*"Payload" concept of operations*



# Building GLaD\*: Bricks and Mortar



\*Global Laboratory Directory

WHA 2006 resolution relative to the immediate and voluntary compliance with IHR (2005)

WHO is requested to... « expand and accelerate training efforts in the areas of laboratory capacity, including ...

regional networking of laboratories,

biosafety, and

quality control... »

## Twelve Quality System Essentials



System  
Essentials

Set of coordinated activities that function as building blocks for quality management.

# WHO: Enhance laboratory biosafety with support of IHR

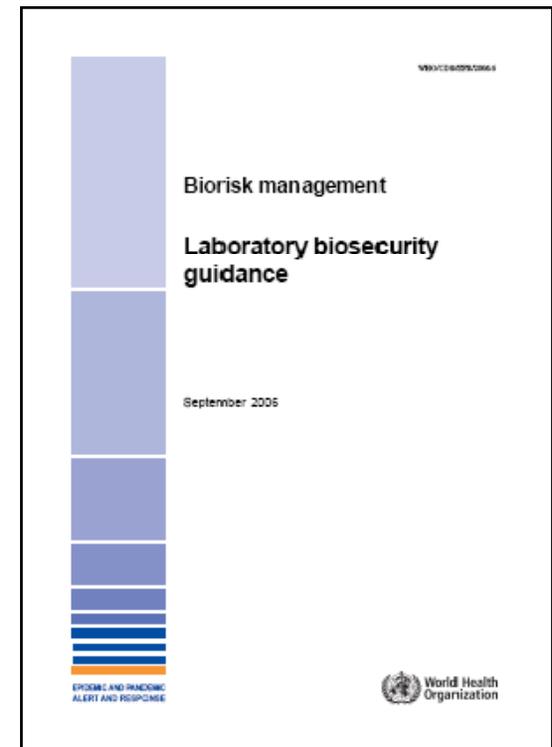
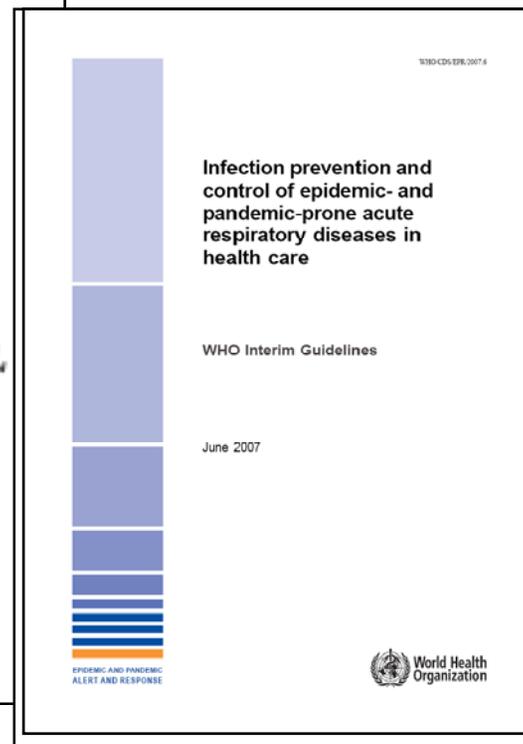
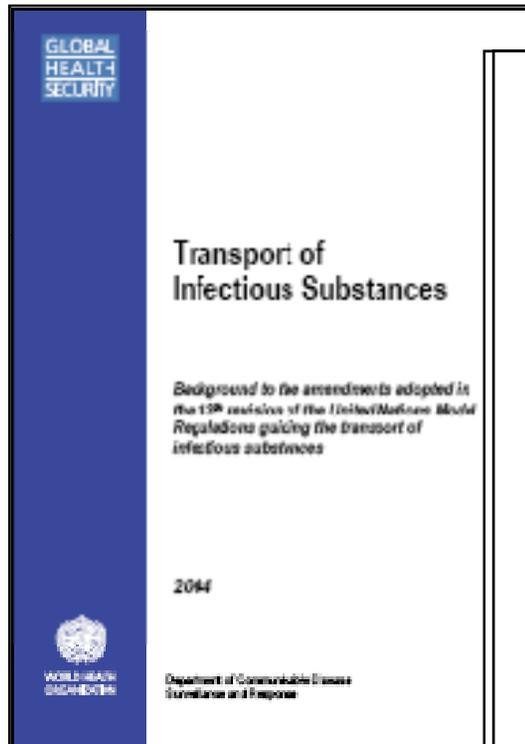
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- Assist Member States to understand, adopt and implement biorisk management strategies in order to minimize risks of infections through safe and secure practices in the laboratory and transport environments, (and to accomplish these goals in a cost-effective manner)
- Ensure efficient transport of infectious substances
- Contain polioviruses in post-eradication era
- Ensure the safe-keeping and preventing the release of variola viruses from the two custodial WHO-designated repositories
- Enhance biosafety and laboratory biosecurity worldwide

# Other WHO biosafety and laboratory biosecurity publications

- translated into FR, SP

- only available in EN

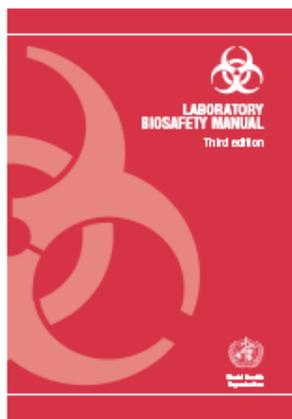


[http://www.who.int/csr/resources/publications/biosafety/en/WHO\\_CDS\\_CSR\\_LYO\\_2004\\_9Final.pdf](http://www.who.int/csr/resources/publications/biosafety/en/WHO_CDS_CSR_LYO_2004_9Final.pdf)

[http://www.who.int/csr/resources/publications/biosafety/WHO\\_CDS\\_EPR\\_2007\\_2/en/index.html](http://www.who.int/csr/resources/publications/biosafety/WHO_CDS_EPR_2007_2/en/index.html)

[http://www.who.int/csr/resources/publications/biosafety/WHO\\_CDS\\_EPR\\_2006\\_6/en/index.html](http://www.who.int/csr/resources/publications/biosafety/WHO_CDS_EPR_2006_6/en/index.html)

# Laboratory biosecurity is a complement of biosafety

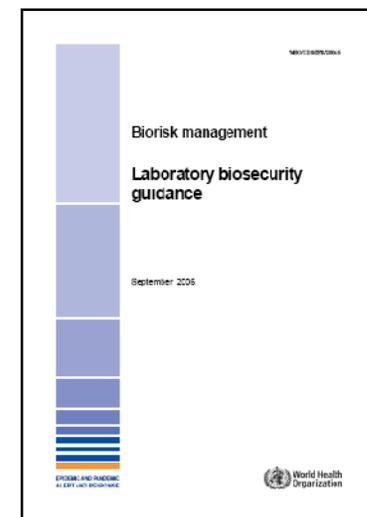


*Laboratory biosafety* describes containment principles, technologies and practices implemented to prevent unintentional exposure to pathogens and toxins, or their accidental release.

[http://www.who.int/csr/resources/publications/biosafety/WHO\\_CDS\\_CSR\\_LYO\\_2004\\_11/en/](http://www.who.int/csr/resources/publications/biosafety/WHO_CDS_CSR_LYO_2004_11/en/)

*Laboratory biosecurity* describes the protection, control and accountability for valuable biological materials (VBM) within laboratories, in order to prevent their unauthorized access, loss, theft, misuse, diversion or intentional release.

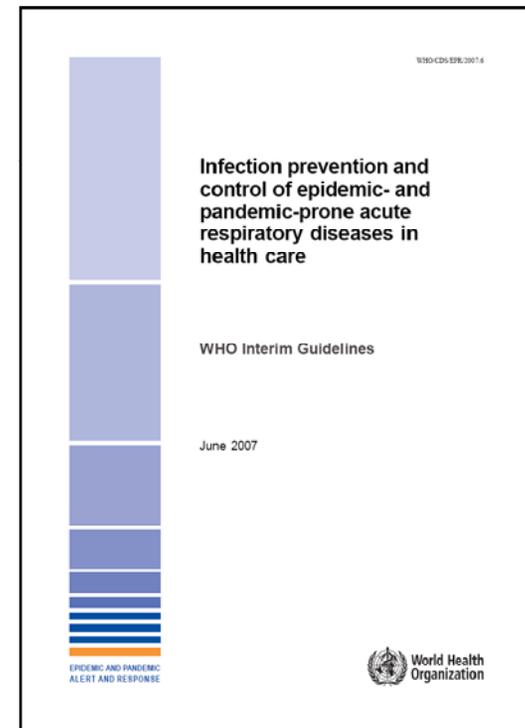
[http://www.who.int/csr/resources/publications/biosafety/WHO\\_CDS\\_EPR\\_2006\\_6/en/index.html](http://www.who.int/csr/resources/publications/biosafety/WHO_CDS_EPR_2006_6/en/index.html)



# WHO publications on closely related subjects

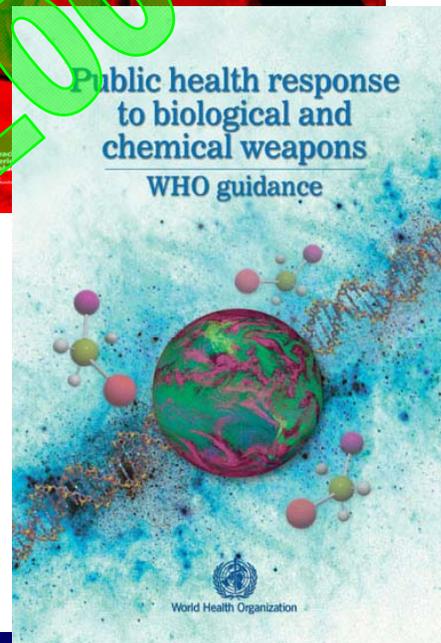
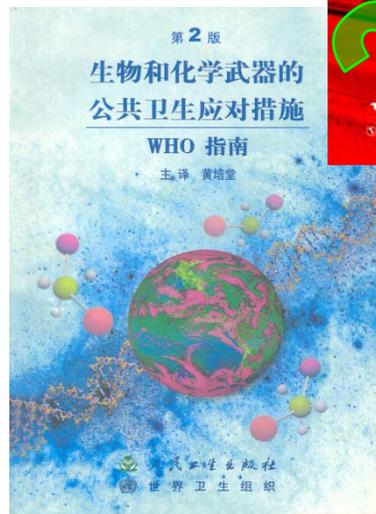
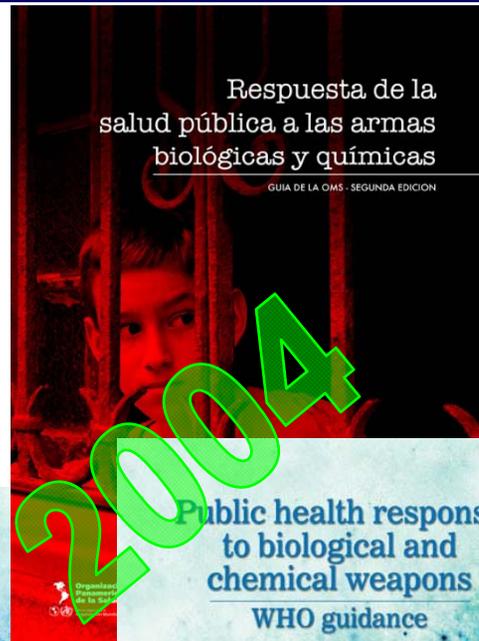
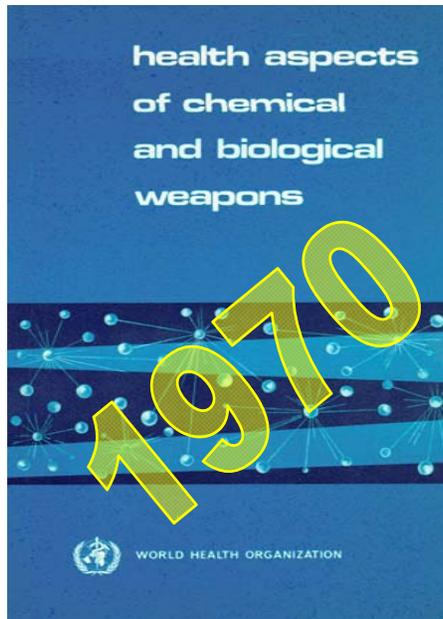
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Infection prevention and control in health care for preparedness and response to outbreaks



[http://www.who.int/csr/resources/publications/WHO\\_CD\\_EPR\\_2007\\_6/en/index.html](http://www.who.int/csr/resources/publications/WHO_CD_EPR_2007_6/en/index.html)

# Guidance for public health preparedness



*Managing the health  
risks of the  
deliberate use of  
biological and  
chemical agents or  
radioactive material:  
Guidance on  
capacity assessment*

# Life science research and global health security

## Objectives

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inform and provide guidance on risk management tools for countries on the prevention of accidental or potential misuse associated with the outputs of life science research – from expected or unexpected products (tangible products) to skills and tacit knowledge (intangible factors).

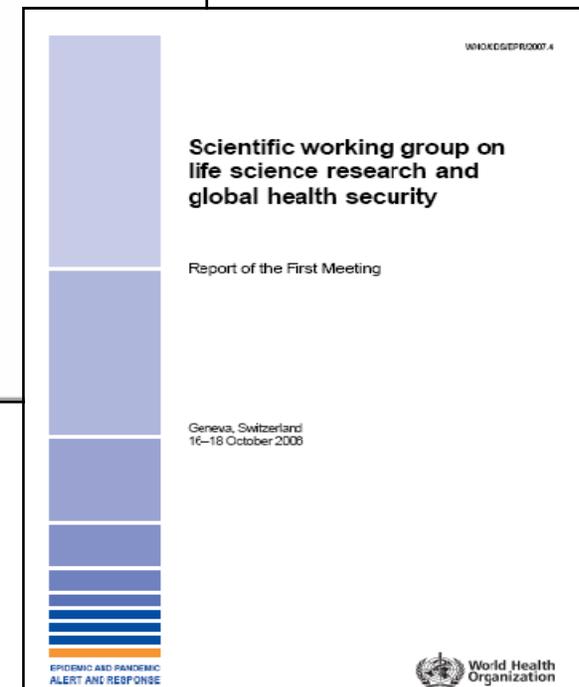
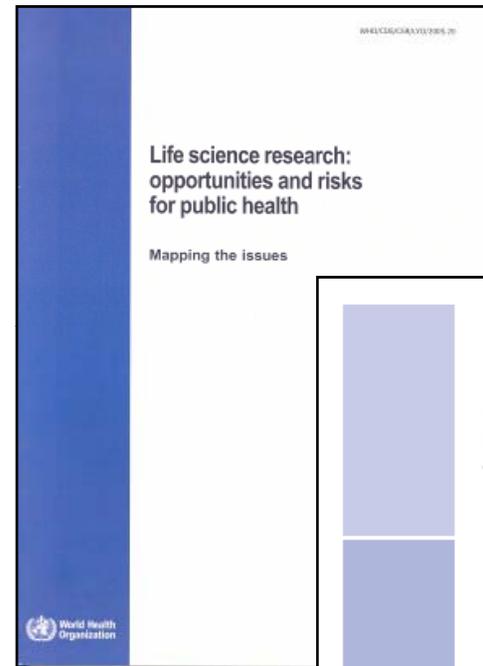
Looking from the public health perspective:

- importance of health research, responsible biomedical research and laboratory biosafety and laboratory biosecurity
- impact on public health
- public confidence in science
- knowledge varies among Member States

# Responsible Biomedical Research - recommendations from recent meetings

## Five areas for action

1. Education and training
2. Preparedness for a possible major outbreak of disease
3. Development of risk assessment methodologies
4. Engagement of all stakeholders in the life science community and guidelines for oversight
5. Capacity building at country level, including ethics, clinical practice, laboratories and research



## Twelve Quality System Essentials



System  
Essentials

Set of coordinated activities that function as building blocks for quality management.

# WHO: Enhance laboratory biosafety with support of IHR

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- Assist Member States to understand, adopt and implement biorisk management strategies in order to minimize risks of infections through safe and secure practices in the laboratory and transport environments, (and to accomplish these goals in a cost-effective manner)
- Ensure efficient transport of infectious substances
- Contain polioviruses in post-eradication era
- Ensure the safe-keeping and preventing the release of variola viruses from the two custodial WHO-designated repositories
- Enhance biosafety and laboratory biosecurity worldwide

# Biosafety Program

Biosafety and Laboratory biosecurity manuals

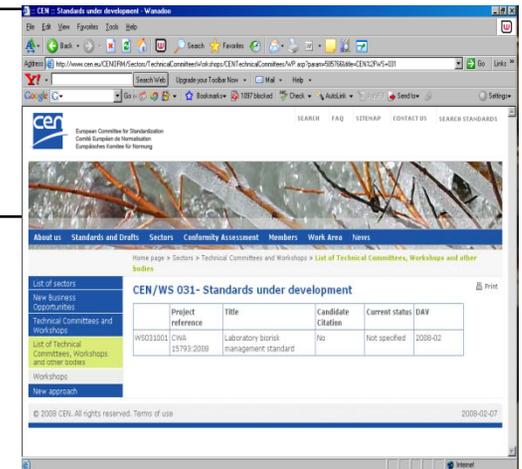
Training and workshops

Collaboration Centers, BAG, Biosafety consortium

Specimen Transport Stakeholders Meeting summary

Issues on the horizon:

- Epidemic of BSL-3 facilities: mapping the issues and solutions
- Access to training: electronic and professional curriculum
- Implementation of CEN CWA 15793:2008



# WHO Biosafety partners and networks

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- Biosafety Advisory Group

- 6 Regional Offices

- 5 Collaborating Centres

Centers for Disease Control and Prevention (USA)

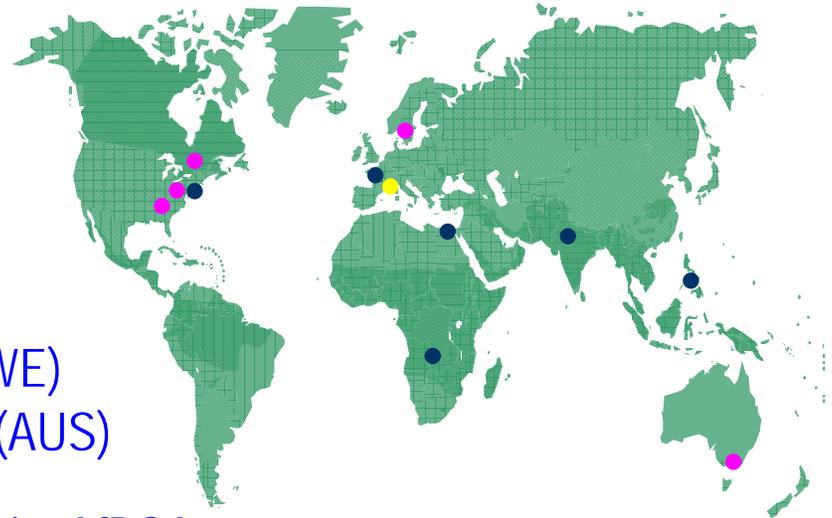
National Institutes of Health (USA)

Public Health Agency of Canada (CAN)

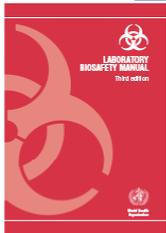
Swedish Institute for Infectious Disease Control (SWE)

Victorian Infectious Disease Reference Laboratory (AUS)

- **Other partners:** ABSA, EBSA, A-PBA, ANBio, AfBSA...

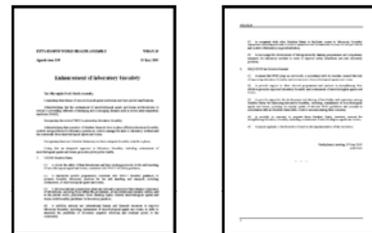


# More than 2 years later: Where are we now?



## Enhancement of laboratory biosafety

May 2005



Through engagement, communication, meetings, workshops, consultations, coordination of global efforts by various stakeholders:  
2008:

- development / revision of legislation (e.g. Singapore / China)
- construction / renovation of laboratories (Brazil: 12 new BSL3)
- showing growing commitment to biosafety principles and practices
- role of laboratory management for biosafety: shift in responsibilities
- need for training support (TT, behavioural changes, etc.)

# Global trend: the appearance of BSL3 facilities I

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Considerations linked to the proliferation of containment facilities:

- Are we actually increasing OR reducing the risks of infections?
- Are we ready to use these laboratories appropriately?
- Do we know how to construct them?
- Do we know what exactly we need?
- Do we know how to maintain them?
- Do we know how to certify them, and who will be accredited to certify them?



# Global trend: the appearance of BSL3 facilities II

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- Do we know what running costs are going to be associated with them?
- Do we know where funding will come from?
- Do we expect to receive samples / materials that require such containment?
- Do we train our current / future staff appropriately?



# Global trend: the appearance of BSL3 facilities III

- Do we expect to share agents / samples with other institutions or countries?
- Do we need to develop agreements on e.g. ownership of the samples / agents?
- Do we need to agree on codes of conduct?  
Dual use issues?

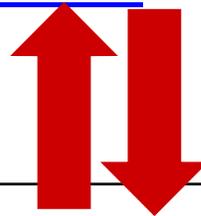
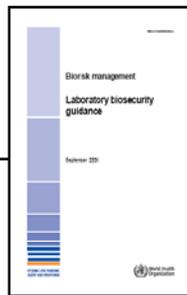


# Support development of national policy

WHO to provide non prescriptive, but performance based guidance with the "Biorisk management" approach:

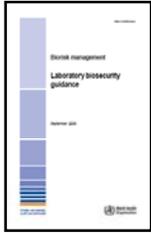
place responsibility on facilities to demonstrate that appropriate risk reduction procedures have been established

clear messages, clear advantages: change in behaviours, development of a "biosafety culture"



Top down – bottom up





## Laboratory biosecurity issues I



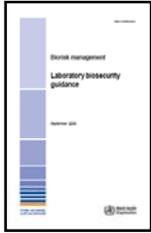
Restrict the biosecurity scope to laboratory environments

Biosafety (**working safely with biological agents**) is the basis for laboratory biosecurity (**accountability and responsibility for valuable biological materials**)

Developing countries have few resources for either biosafety or biosecurity: risk and threat assessments

Implementable, sustainable, global biosecurity measures must be developed through consensus with clear advantages to participants





## Laboratory biosecurity issues II

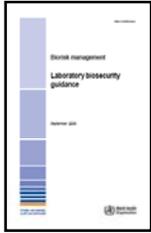
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Bioscience facilities working with pathogens, toxins and other valuable biological materials (VBM):

- Diagnostic and clinical (human health care) laboratories
- Basic and applied research laboratories
- Veterinary and agricultural laboratories
- Pharmaceutical and biotechnology laboratories

Bioscience community is not uniformly accustomed to security issues

Global norms and standards for professional conduct do not exist



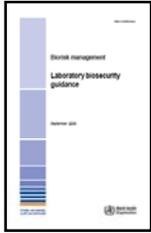
## Laboratory biosecurity issues III

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Global regulatory mechanisms for biological materials do not exist ... yet (possession, use, oversight, import, containment, registration, inspections, certification)

Security and control measures must be in balance with other priority public goods

Biosafety vs Biorisk management: a shift in responsibilities



# Guidance on Laboratory Biosecurity

## Biorisk management approach

### Needs

Awareness of issue

Commitment to action

"Top down" and "Bottom up" approach

Consensus on fundamental laboratory biosecurity standards

### Desired Outcomes

Common basis for future approaches to biosecurity

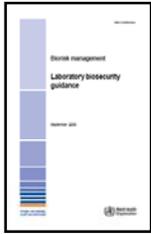
Facilitation of research and collaboration

Common mechanisms for exchange of valuable biological materials and information

Involvement of diverse members of the scientific community (health, agriculture, research, biotech industry, pharma)

Improved laboratory biosecurity

# Biorisk Management: Laboratory Biosecurity Guidance



## Summary

"Guidance" vs "guidelines": raise points for consideration

Address valuable biological materials

Involve stakeholders (scientists, local management, biosafety officers, maintenance staff, IT staff, administrators and law-enforcement representatives) to assess risks and threats

Adapt laboratory biosecurity measures to identified needs

Based on responsibility and accountability

Not prescriptive, but performance based

Zero risk is not achievable

No punitive actions

# WHO's support: Strengthen "Biorisk Management" in all Regions

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Organize Biosafety and Laboratory Biosecurity

Awareness Raising Workshops



# Typical structure of Biosafety and Laboratory Biosecurity Awareness Raising Workshops

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Composition of national delegations:

- MoH, access to regulatory framework
- Director of central human public health laboratory
- Director of central animal health laboratory

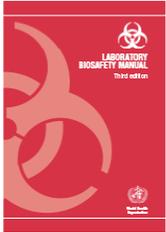
Discuss:

1. Laboratory management and legislative framework
2. Physical environment: equipment, construction, design for human and animal research, containment
3. Networking, training and human resources
4. Biorisk management: biosafety and laboratory biosecurity, and responsible biomedical research

Develop: Regional plans, commitments, national plans

Train: Transport of infectious substances

# Training and training materials



Train the Trainers Manual, based on LBM3

Risk assessment guidelines

Use of biosafety cabinets

Maintenance and operation of biosafety equipment

Transport of infectious substances, e-tool



# Other tools to implement biosafety, laboratory biosecurity and biorisk management

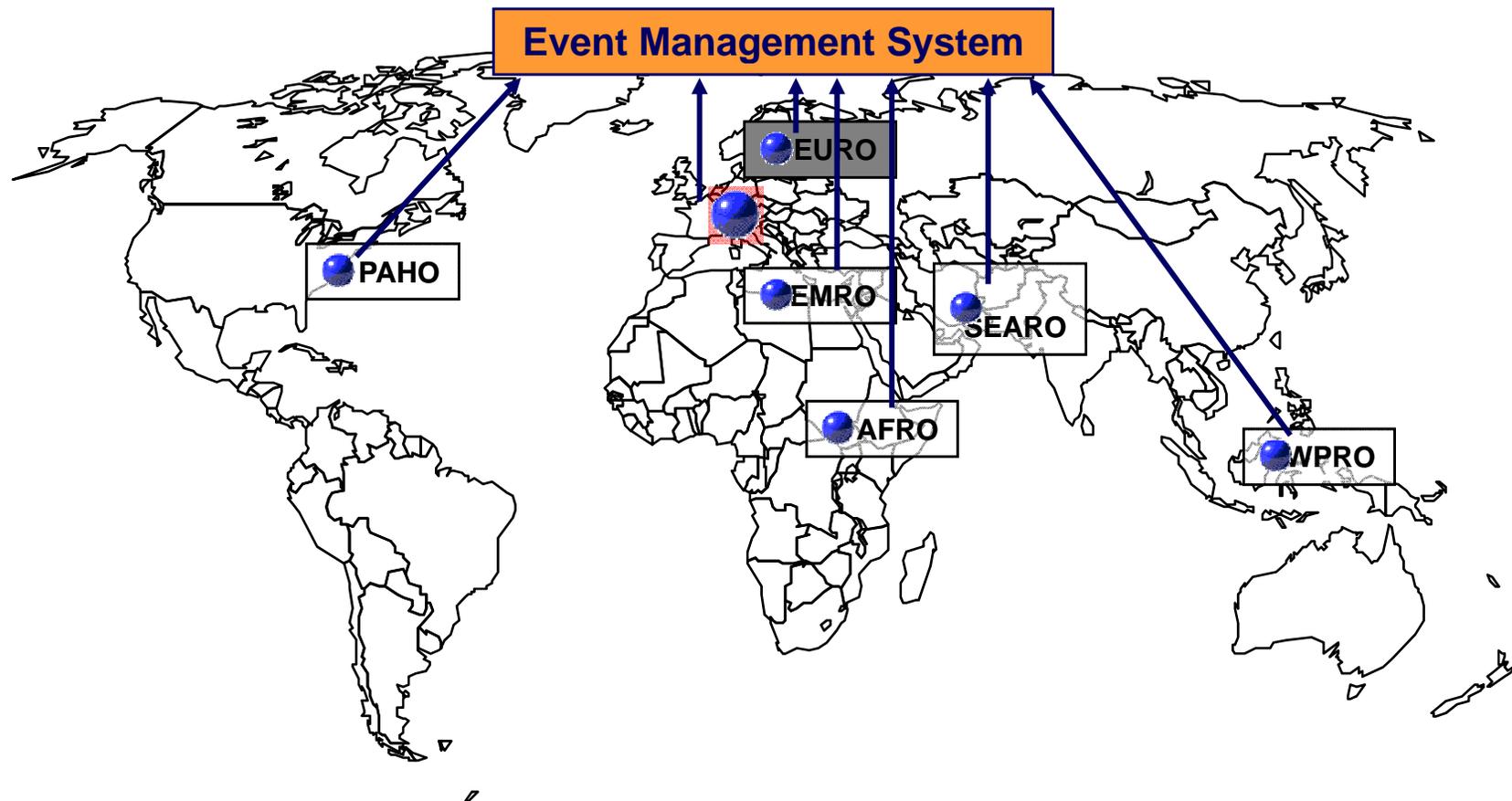
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Introduction of biosafety classes into undergraduate / graduate studies for life sciences, engineering, architecture, etc....

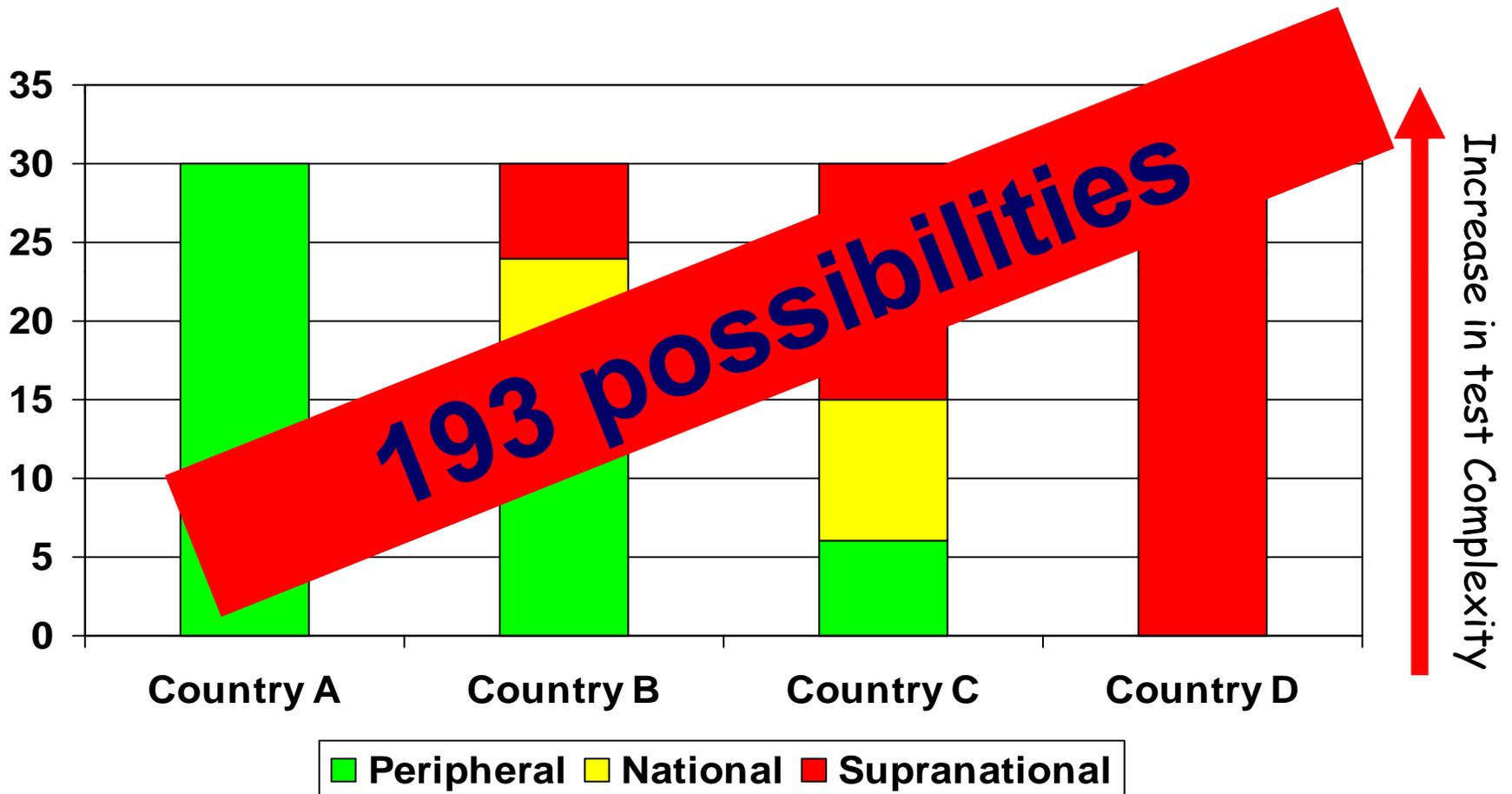
Development and implementation of a curriculum for biosafety professionals

International recognition and certification of laboratories: CEN Laboratory Biorisk Management Standard

# Information flow, national IHR focal points to WHO



# Laboratory capacities for IHR



# Approaches to Capacity Building

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## ● Conventional:

- Guidance
- Assessment (self or visit)
- Partnership and twinning
- Training
- Norms and standards
- Individually, country by country

## ● Networking

- Virtual and Face-to-Face, platform-based
- Regional and sub-regional
- Supporting existing networks, building networks, sustain networks
- Confidence-building measures

## ● Functional Assessment

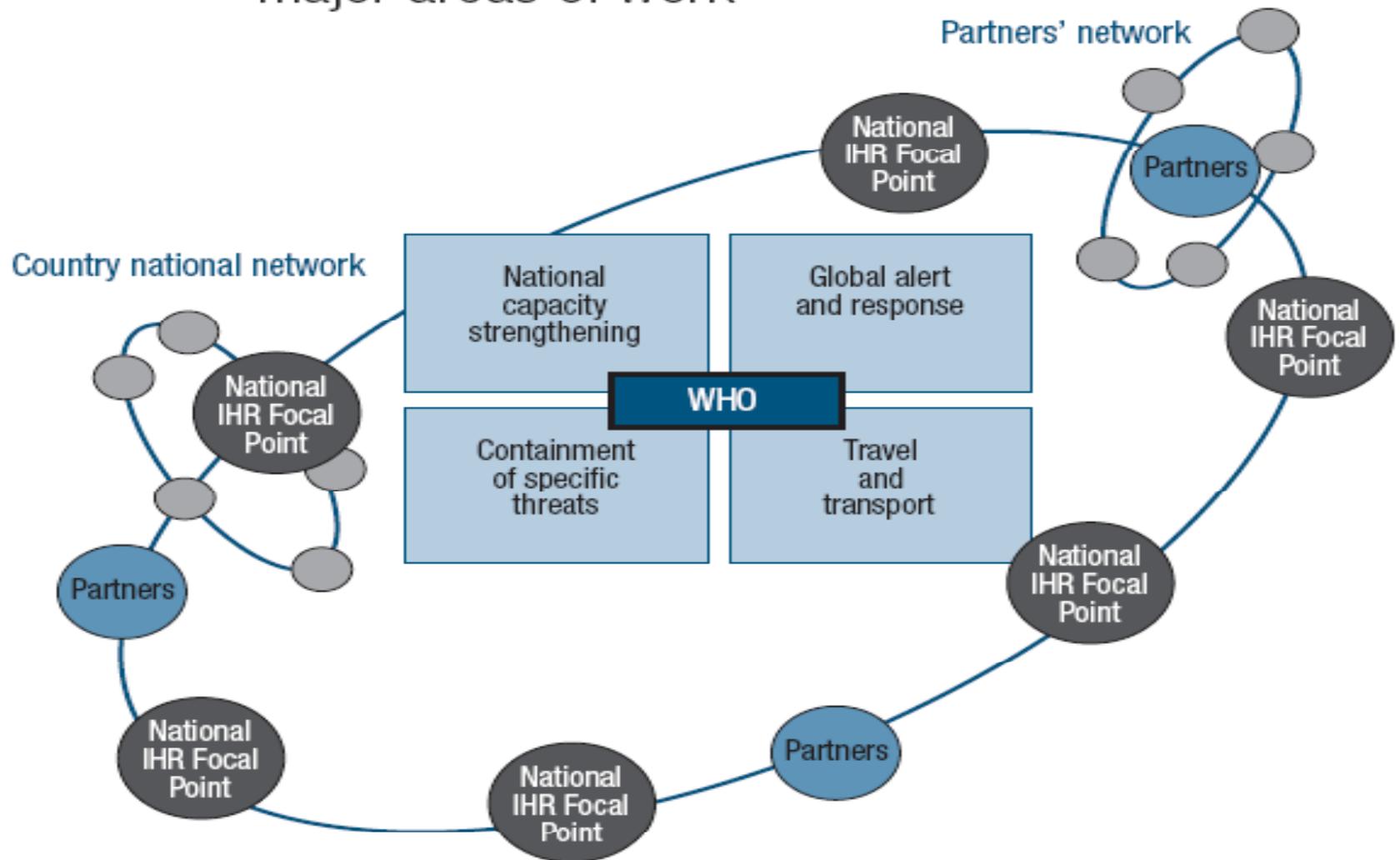
- Multidisciplinary, extends beyond traditional health sector
- Exercise, scenario play-book
- Quality management systems
- Legislative

# Using the full power of the IHR

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- It is the only international regulatory mechanism that binds the 194 State Parties
- WHO and the State Parties must demonstrate their commitment by applying the spirit of the IHR
- We must find ways to incentivize application and encourage compliance
- Capacity equity must be a goal among State Parties to build respect and confidence

Figure 1.3 International public health security: a global network of national health systems and technical partners, coordinated by WHO, founded on four major areas of work





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# THANK YOU

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