

*Biosecurity Workshop , 22-24 February 2009, Alexandria, Egypt*

# International Health Security, WHO's Strategies on Dual use issues

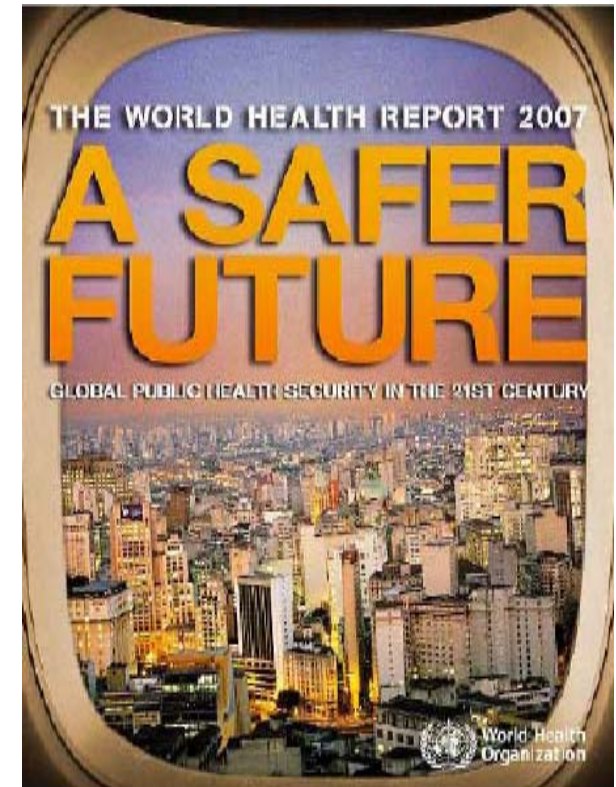
**Dr Ali A. Mohammadi**  
**Scientist**

**Laboratory Alliance and Biosafety**  
**International Health Regulations**  
**World Health Organization**

# Lessons from the 2007 WHO World Health Report:

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**“Global Public  
Health Security  
- A Safer Future”**



# Global public health security – a definition

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"Global public health security minimizes vulnerability to acute public health events that endanger the collective health of populations living across geographical regions and international boundaries, and includes the impact on economic, political stability, trade, tourism, access to goods and services and demographic stability."

# Findings from the World Health Report 2007 (1)

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- . 685 verified events of international public health concern occurred from September 2003 to September 2006 (a mean of about 5 PHEICs each week)
- Infectious diseases emerged at a rate of one or more a year since the 1970s, including Avian Flu, SARS, also Ebola, Marburg and Nipah viruses
- Depending on a number of factors, a highly pathogenic Flu pandemic could affect more than 1.5 billion people or 25% of the world population

# Spectrum of Microbial Threats

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Newly recognized pathogens

New geographical spread

Resurgence of endemic infections

Antimicrobial-resistant infections

Infectious etiology of chronic diseases

Intentional use of biological agents

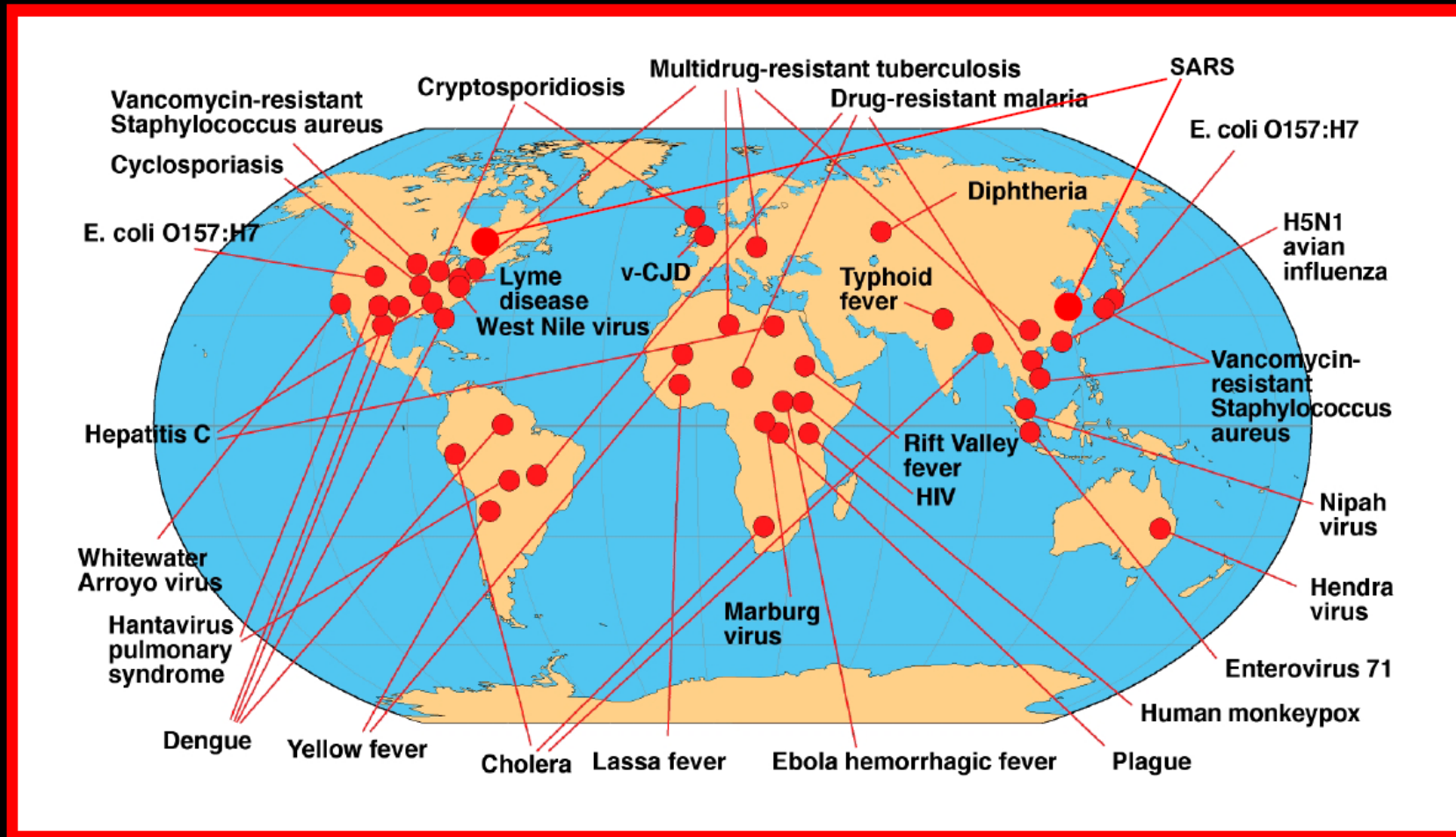
# Leading Infectious Causes of Death Worldwide

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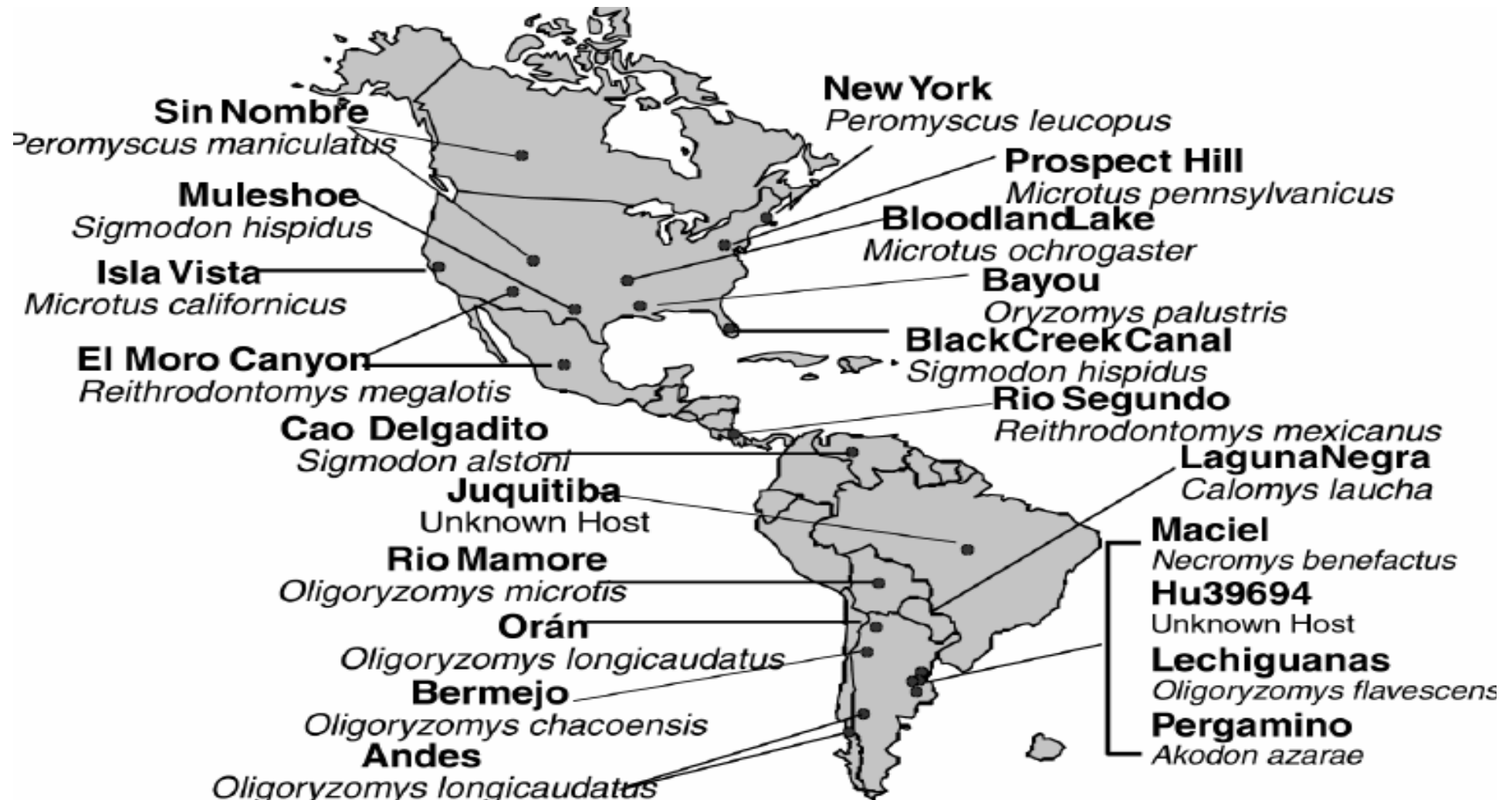
Cause	Rank	Number of Deaths
Respiratory infections	1	3,871,000
HIV/AIDS	2	2,866,000
Diarrhoeal diseases	3	2,001,000
Tuberculosis	4	1,644,000
Malaria	5	1,124,000
Measles	6	745,000
Pertussis	7	285,000
Tetanus	8	282,000
Meningitis	9	173,000
Syphilis	10	167,000

Source: WHO, 2002

# Recent Microbial Threats



# New World Hantavirus





# Factors in Emergence (1)

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Human demographics and behavior

Technology and industry

Economic development and land use

International travel and commerce

Microbial adaptation and change

Breakdown of public health measures

# Factors in Emergence (2)

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Human susceptibility to infection

Climate and weather

Changing ecosystems

Poverty and social inequality

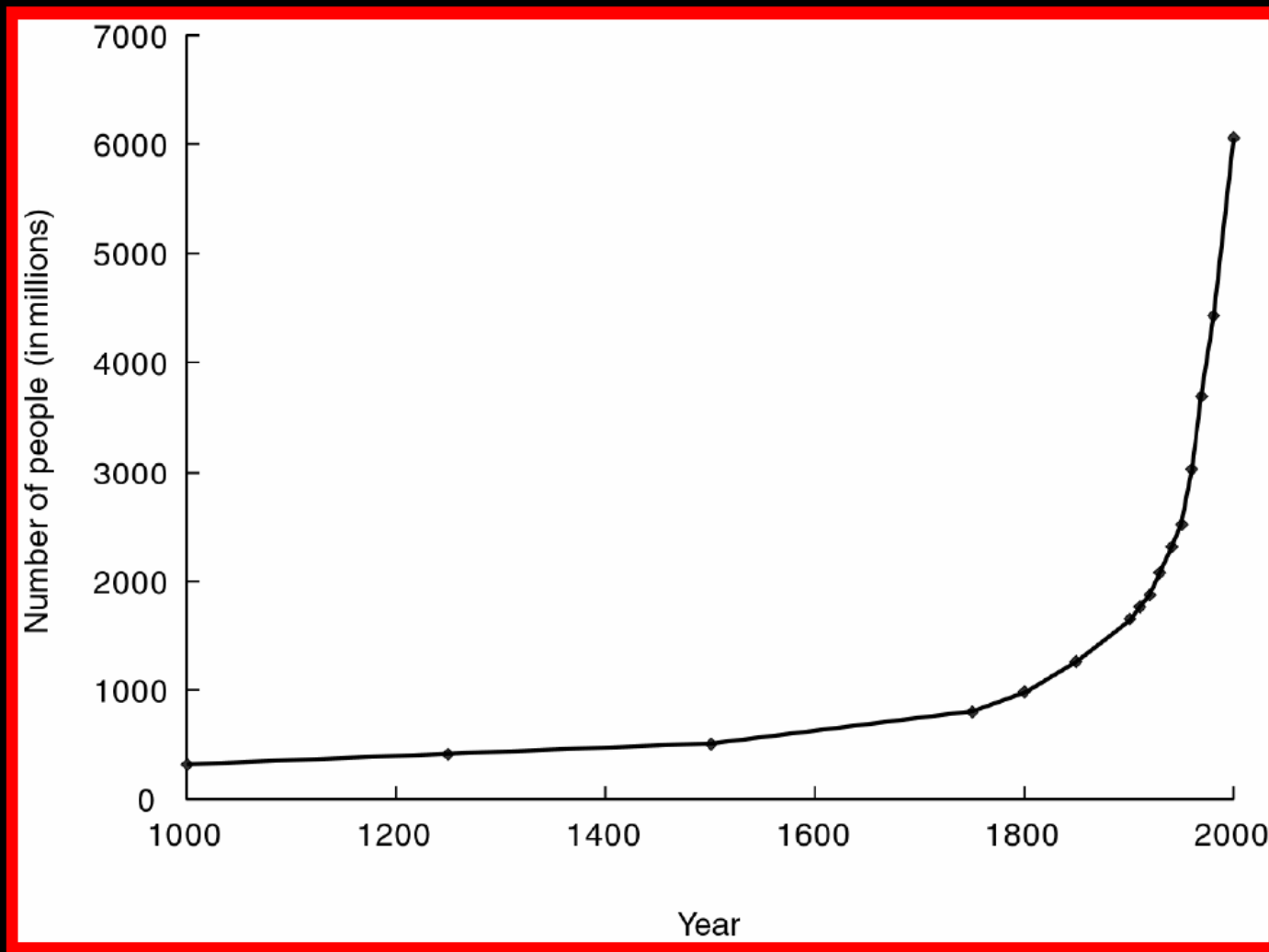
War and famine

Lack of political will

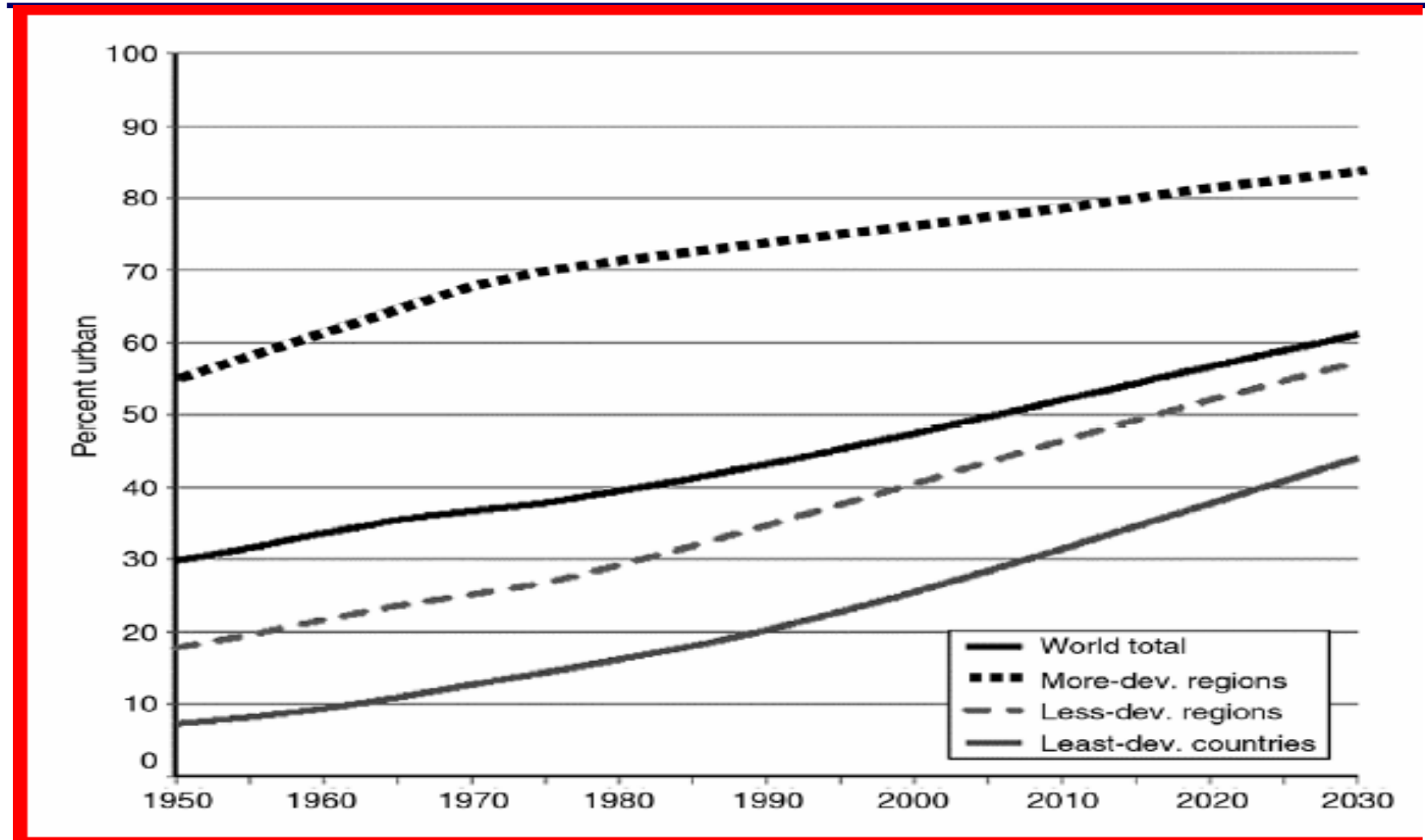
Intent to harm

# The Human Population Explosion

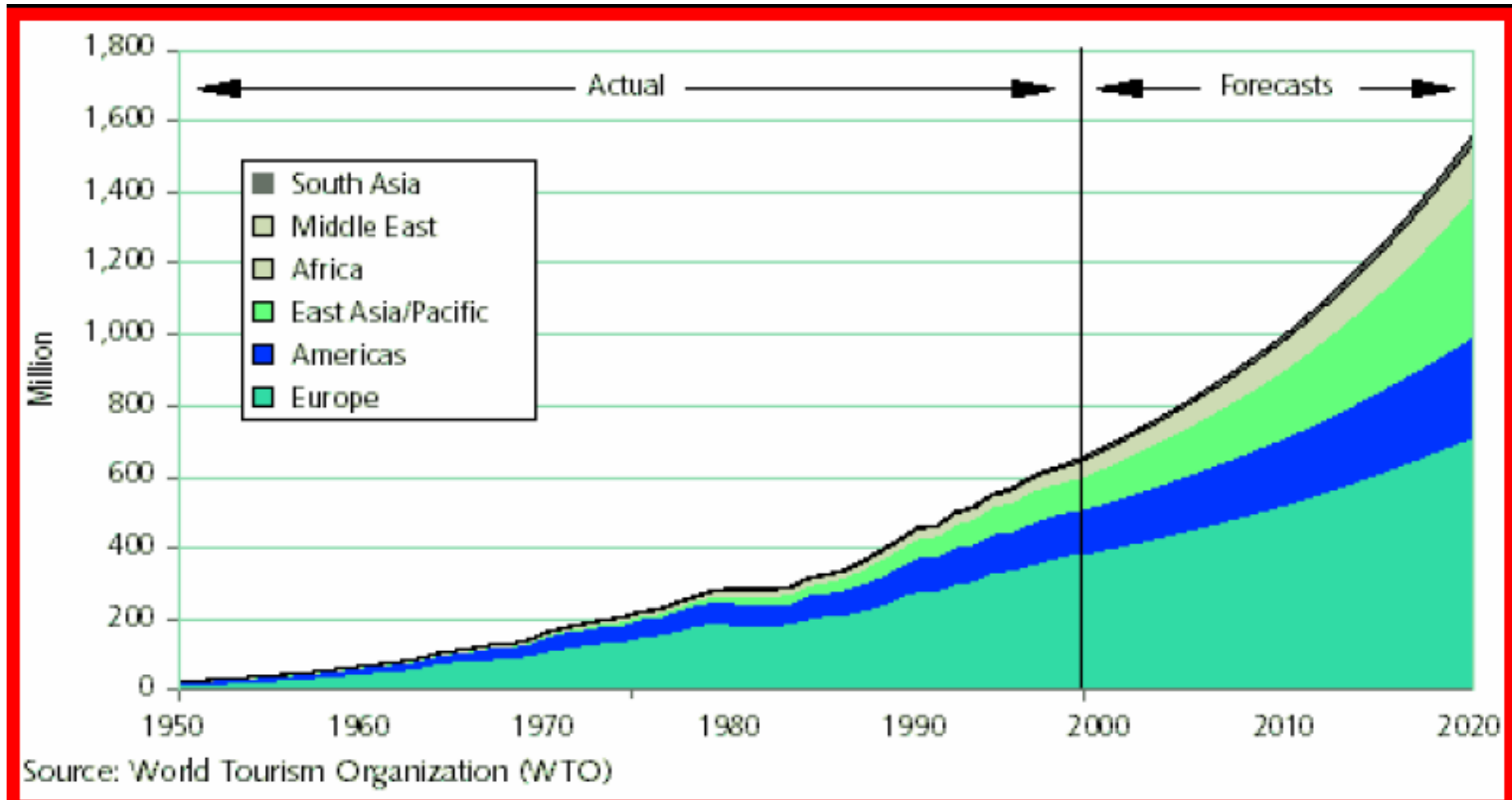
Source: UN, 1999



# World Urbanization Trends



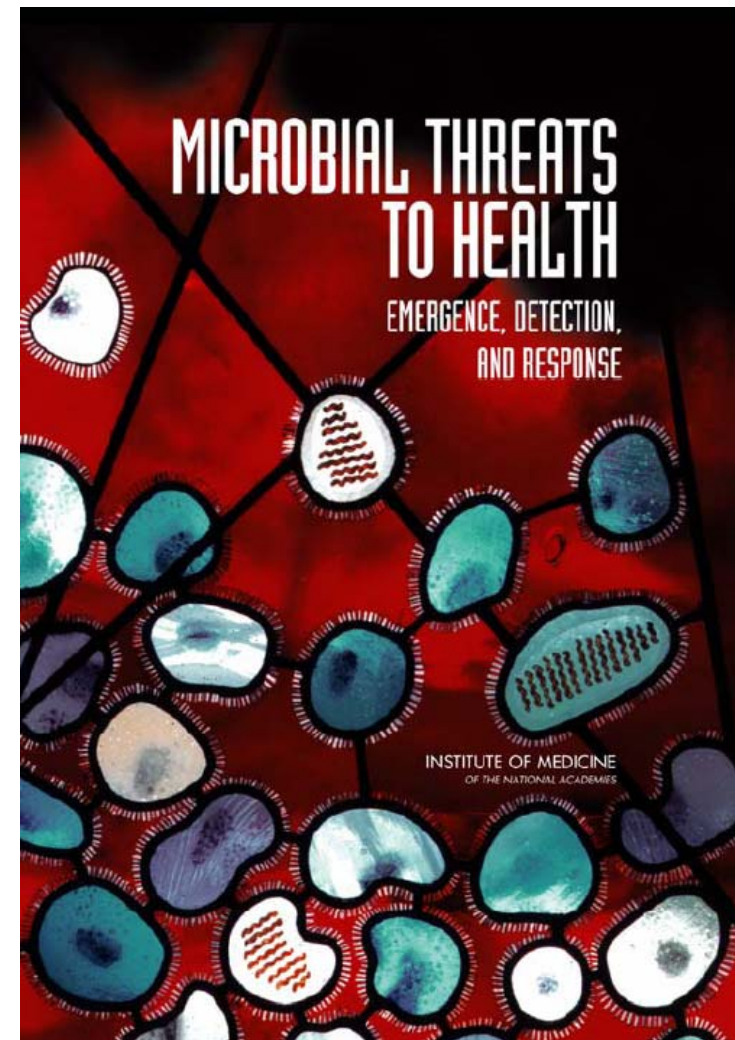
# International Tourists Arrivals



WTO, 2002

# Best Defense

The best defense against any Microbial threat is a robust public Health system—in its science, capacity, practice, and through its collaborations with clinical and veterinary medicine, academia, industry, and other public and private partners.



# Global Health Security and Biorisk Management

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## Security Council Press Release SC/6781 (January 2000)

- Security Council debate on impact of aids on peace and security in Africa.

## World Health Assembly resolution 54.14 (May 2001)

- "Resolution on Global Health Security: Epidemic Alert and Response"

## World Health Assembly resolution 55.16 (May 2002)

- "Global public health response to natural occurrence, accidental release or deliberate use of biological and chemical agents or radionuclear material that affect health"

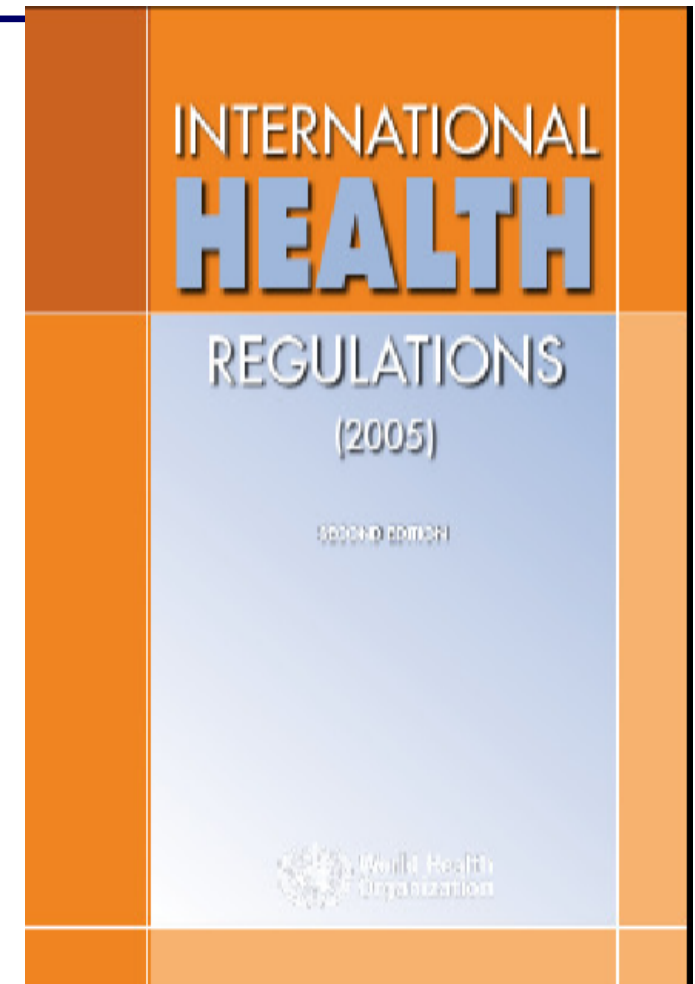
## International Health Regulations (May 2005)

- "public health emergency of international concern"
- If a State Party has evidence of an unexpected or unusual public health event within its territory, irrespective of origin or source, which may constitute a public health emergency of international concern, it shall provide to WHO all relevant public health information" (WHA58.3, 2005).

# International Health Regulations — 2005

## The International Health Regulations (IHR)

- 1851: First international sanitary conference, Paris
- 1969: International Health Regulations
- 2005: IHR (2005) adopted by the World Health Assembly
- 2007: IHR enters into force
- 2009: Countries complete assessment of capacities
- 2012: Implementation of national capacity plan





# Global health security and IHR (2005)



New framework and legally-binding agreement for all 194 WHO Member States (193 countries and the Vatican)

Purpose and scope: "are to prevent, protect against, control and provide a public health response to the international spread of disease in ways that are commensurate with and restricted to public health risks, and which avoid unnecessary interference with international traffic" (Article 2)

Requires countries to develop minimum **core capacities** for national and international surveillance and reporting —National **core capacities** for detection and response

Broaden notification from cholera, plague and yellow fever to include all threats (Annex 2)

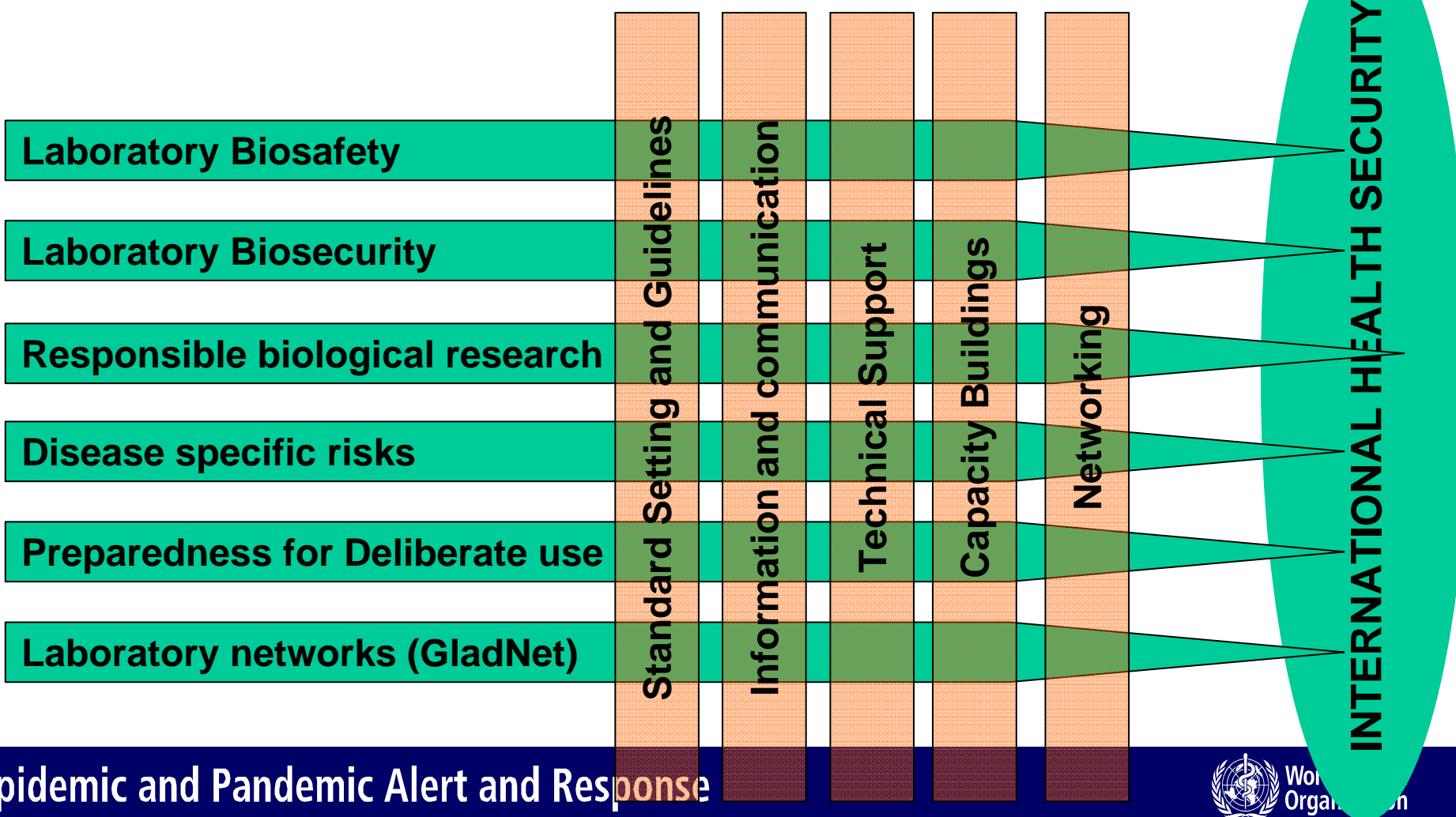
Communication and notification by designated National IHR Focal Points

WHO will provide international assistance, at the request of Member States, in support of activities

# WHO Biorisk Reduction Management

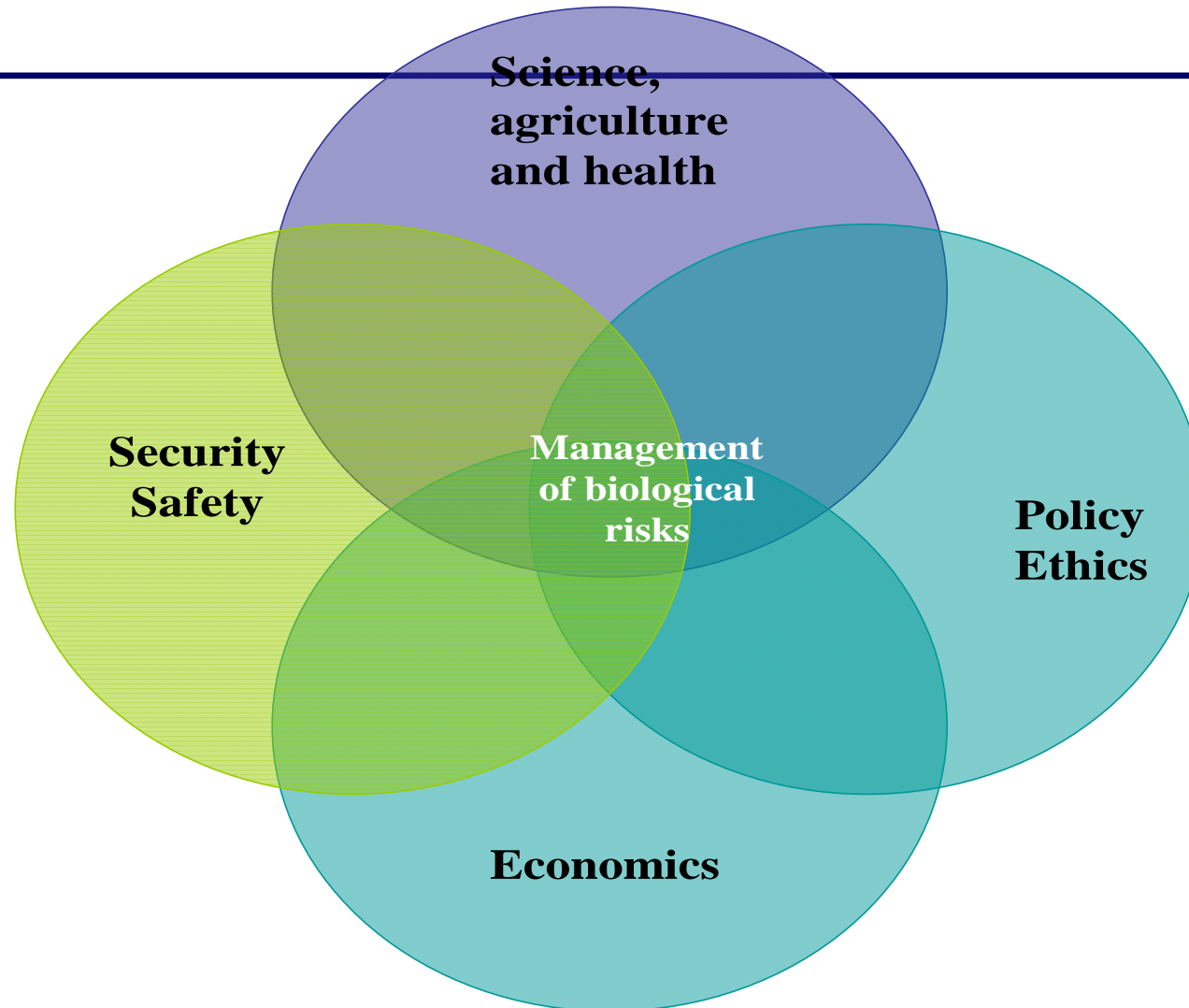
## Functions

## Activities



# The wider biosecurity context: a multi-stakeholder issue

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# WHO Biosafety programme

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## WHO Biosafety:

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



# WHO Biosafety: Objectives

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## Biosafety:

To promote the use of safe practices in the handling of pathogenic microorganisms

- in the laboratory
- during transportation
- in field investigations
- in manufacturing facilities
- in health-care facilities

# Laboratory Accidents and Bio-Risks

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- Small Pox: UK, 1978
- SARS: Singapore, 2003
- SARS: Taiwan, 2003
- SARS: China, 2004
- Tularaemia: USA, 2004
- Ebola: Russia, 2004
- Influenza: USA, 2005



## Among the previously undisclosed accidents:

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- **In Rockville, Md., ferret No. 992, inoculated with bird flu virus, bit a technician at Bioqual Inc. on the right thumb in July. The worker was placed on home quarantine for five days and directed to wear a mask to protect others.**
- **An Oklahoma State University lab in Stillwater in December could not account for a dead mouse inoculated with bacteria that causes joint pain, weakness, lymph node swelling and pneumonia. The rodent - one of 30 to be incinerated - was never found, but the lab said an employee "must have forgotten to remove the dead mouse from the cage" before the cage was sterilized.**

## Among the previously undisclosed accidents:

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- **In Albuquerque, N.M., an employee at the Lovelace Respiratory Research Institute was bitten on the left hand by an infected monkey in September 2006. The animal was ill from an infection of bacteria that causes plague. "When the gloves were removed, the skin appeared to be broken in 2 or 3 places," the report said. The worker was referred to a doctor, but nothing more was disclosed.**
- **In Fort Collins, Colo., a worker at a federal Centers for Disease Control and Prevention facility found, in January 2004, three broken vials of Russian spring-summer encephalitis virus. Wearing only a laboratory coat and gloves, he used tweezers to remove broken glass and moved the materials to a special container.**









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# Laboratory Acquired Infections

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Historically:

- only 20% from recognised accidents
- 80% unknown, ie no recognised accident or knowledge of how transmission occurred

# Most frequently recognised causes of accidents (the 20%)

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- needles / syringes
- spills of infectious material
- injury from infected broken glass
- pipetting
- bites from infected animals
- centrifuge accidents

# Remaining 80% of infections due to aerosols

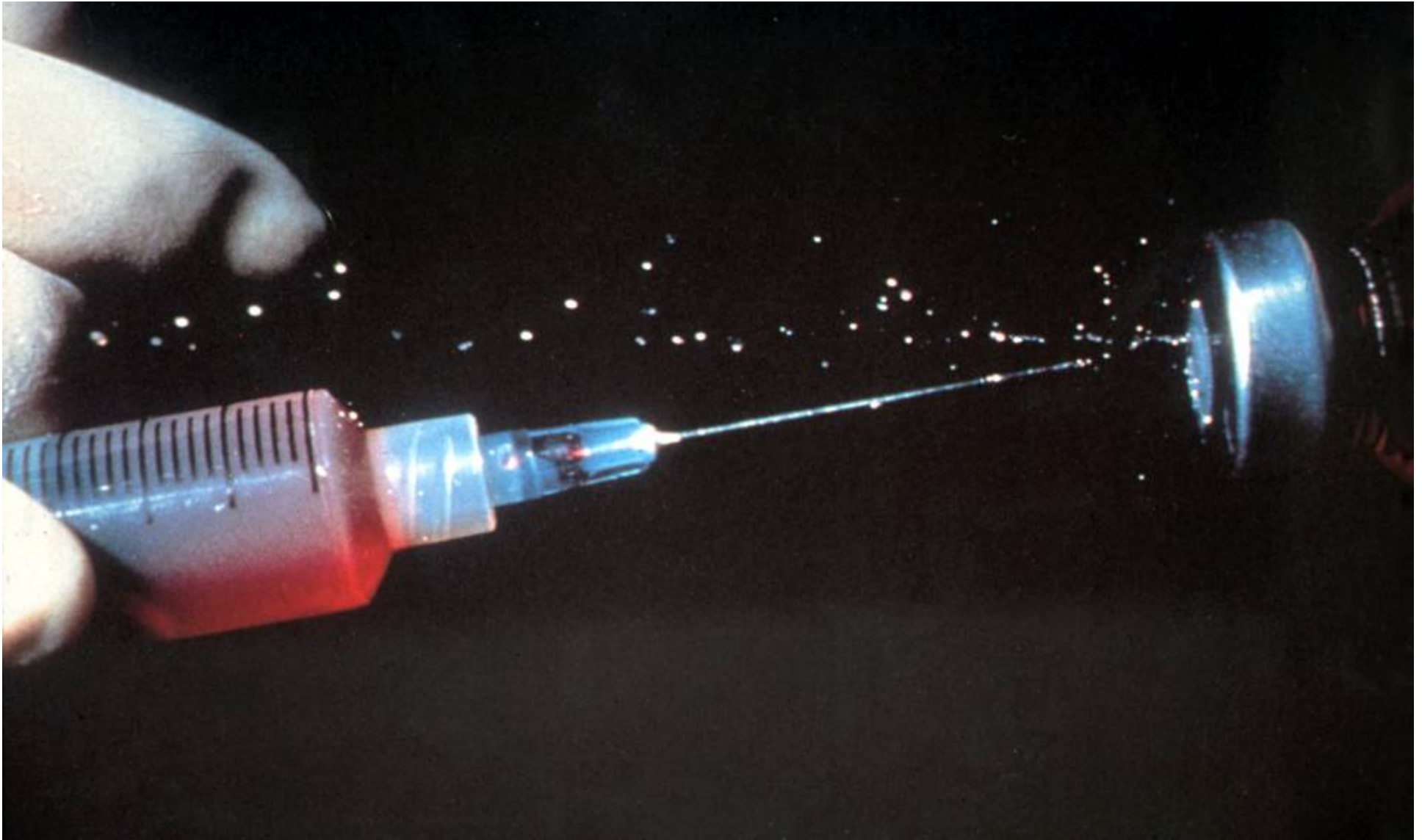
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- Vortexing
- Sonication
- Homogenisation
- Dropping cultures of high titre/spills
- Blowing out drops in pipettes
- Removing needles from syringes/rubber seals



# Withdrawing Syringe from Vaccine- Stoppered Bottle

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A medical care clinic in .....working on  
Crimean–Congo haemorrhagic fever (CCHF)



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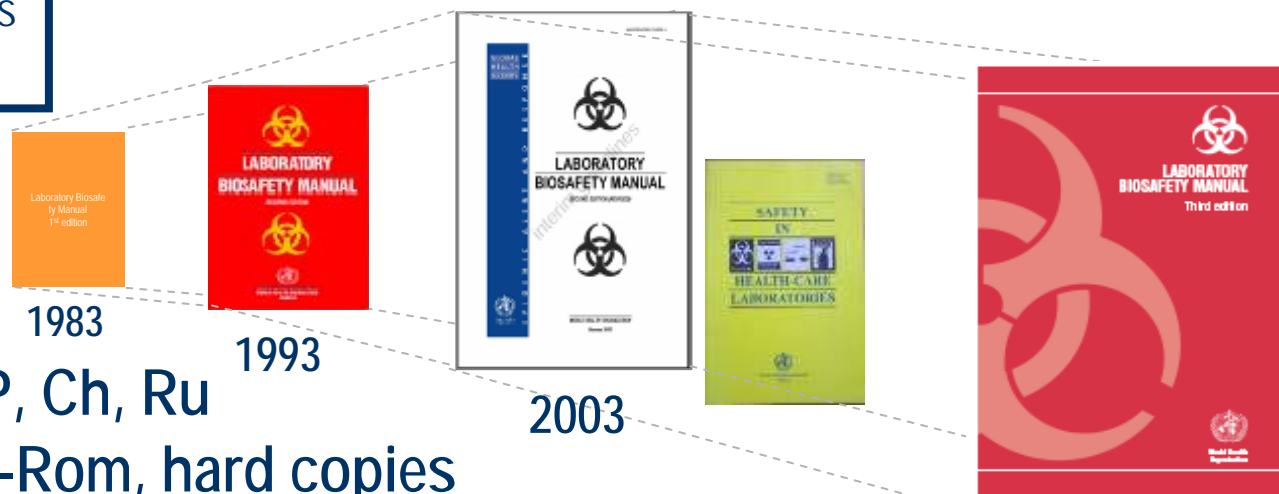
# WHO Laboratory Biosafety Manual

## Biosafety:

To promote the use of safe practices in the handling of pathogenic microorganisms

- in the laboratory
- during transportation
- in field investigations
- in manufacturing facilities
- in health-care facilities

- **Laboratory Biosafety Manual, 3rd edition**
  - lab commissioning and certification
  - lab biosecurity concepts



- translated into F, S, P, Ch, Ru
- available on web, CD-Rom, hard copies



## Enhancement of laboratory biosafety

**FIFTY-EIGHTH WORLD HEALTH ASSEMBLY**                      **WHA58.29**  
**Agenda item 13.9**    **25 May 2005**

**Enhancement of laboratory biosafety**

The Fifty-eighth World Health Assembly,

Considering that release of microbiological agents and toxins may have global ramifications,

Acknowledging that the containment of microbiological agents and toxins in laboratories is critical to preventing outbreaks of emerging and re-emerging diseases such as severe acute respiratory syndrome (SARS),

Recognizing the work of WHO in promoting laboratory biosafety,

Acknowledging that a number of Member States do have in place effective laboratory biosafety controls and guidelines for laboratory practice in order to manage the risks to laboratory workers and the community from microbiological agents and toxins,

Recognizing that some Member States may not have adequate biosafety controls in place,

Noting that an integrated approach to laboratory biosafety, including containment of microbiological agents and toxins, promotes global public health,

1. URGES Member States:

- (1) to review the safety of their laboratories and their existing protocols for the safe handling of microbiological agents and toxins, consistent with WHO's biosafety guidelines;
- (2) to implement specific programmes, consistent with WHO's biosafety guidelines, to promote biosafety laboratory practices for the safe handling and storage, including containment, of microbiological agents and toxins;
- (3) to develop national preparedness plans and national programmes that enhance compliance of laboratories, including those within the government, at universities and research centres, and in the private sector, particularly those handling highly virulent microbiological agents and toxins, with biosafety guidelines for laboratory practices;
- (4) to mobilize national and international human and financial resources to improve laboratory biosafety, including containment of microbiological agents and toxins, in order to minimize the possibility of laboratory-acquired infections and resultant spread to the community.

**RESOLUTION**

- (5) to cooperate with other Member States to facilitate access to laboratory biosafety equipment, including personal protective equipment and containment devices, for the prevention and control of laboratory-acquired infections;
- (6) to encourage the development of biological-safety training programmes and competency standards for laboratory workers in order to improve safety awareness and safe laboratory practices;

2. REQUESTS the Director-General:

- (1) to ensure that WHO plays an active role, in accordance with its mandate, towards the task of improving laboratory biosafety and containment of microbiological agents and toxins;
- (2) to provide support to other relevant programmes and partners in strengthening their efforts to promote improved laboratory biosafety and containment of microbiological agents and toxins;
- (3) to provide support to the development and sharing of knowledge and experience among Member States for enhancing laboratory biosafety, including containment of microbiological agents and toxins, including the regular update of relevant WHO guidelines and manuals in consultation with all Member States with a view to accommodating their concerns;
- (4) to provide, in response to requests from Member States, technical support for strengthening laboratory biosafety, including containment of microbiological agents and toxins;
- (5) to report regularly to the Executive Board on the implementation of this resolution.

Ninth plenary meeting, 25 May 2005  
A58/V19

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## WHA58.29 urges Member States to

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- review the safety of their laboratories and their existing protocols
- promote biosafety laboratory practices for the safe handling and transport
- enhance compliance of laboratories with biosafety guidelines
- minimize the possibility of laboratory acquired infections and resultant spread to the community
- ensure access to PPE and containment devices
- develop biosafety training programmes

**Member States agreed to strengthen biosafety**

## WHA58.29 requests the Director General to:

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- ensure WHO's active role in improving laboratory biosafety
- support other programmes in improving laboratory biosafety
- support sharing of knowledge and experience among States
- consult States in development of WHO guidance materials
- provide technical support for strengthening biosafety
- Report regularly to the EB on implementation of resolution

**WHO is requested to support global biosafety strengthening**

# Biosafety activities

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- biosecurity awareness in WHO regions through the organization of workshops
- Support to national development of policies
- Strengthening biosafety and laboratory Training materials for biosafety TTM and for the shipping of infectious materials
- Addressing biosafety for TB, Polio and smallpox
- CEN Laboratory Biorisk Management standard CWA 15793
- Introduction of biosafety and biosecurity in scientific discipline into undergraduate / graduate studies

# Biosafety activities

- **The WHO Laboratory biosafety and laboratory biosecurity awareness raising regional workshops**
  - Central and South America (Brazil, 2005, 9 countries and Guatemala, 2006, 10 countries)
  - Iran (2006, 22 countries)
  - Kenya (2007, 21 countries, English-speaking)
  - India (2008, 7 countries)
  - Malaysia (2008, 8 countries)
  - Kenya (2008, 24 countries French-speaking)
  - Forthcoming East Europe, CIS

# Personal Protective Equipment (PPE)

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**PPE is not panacea!**



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# Public Health and security activities have traditionally had minimal overlap



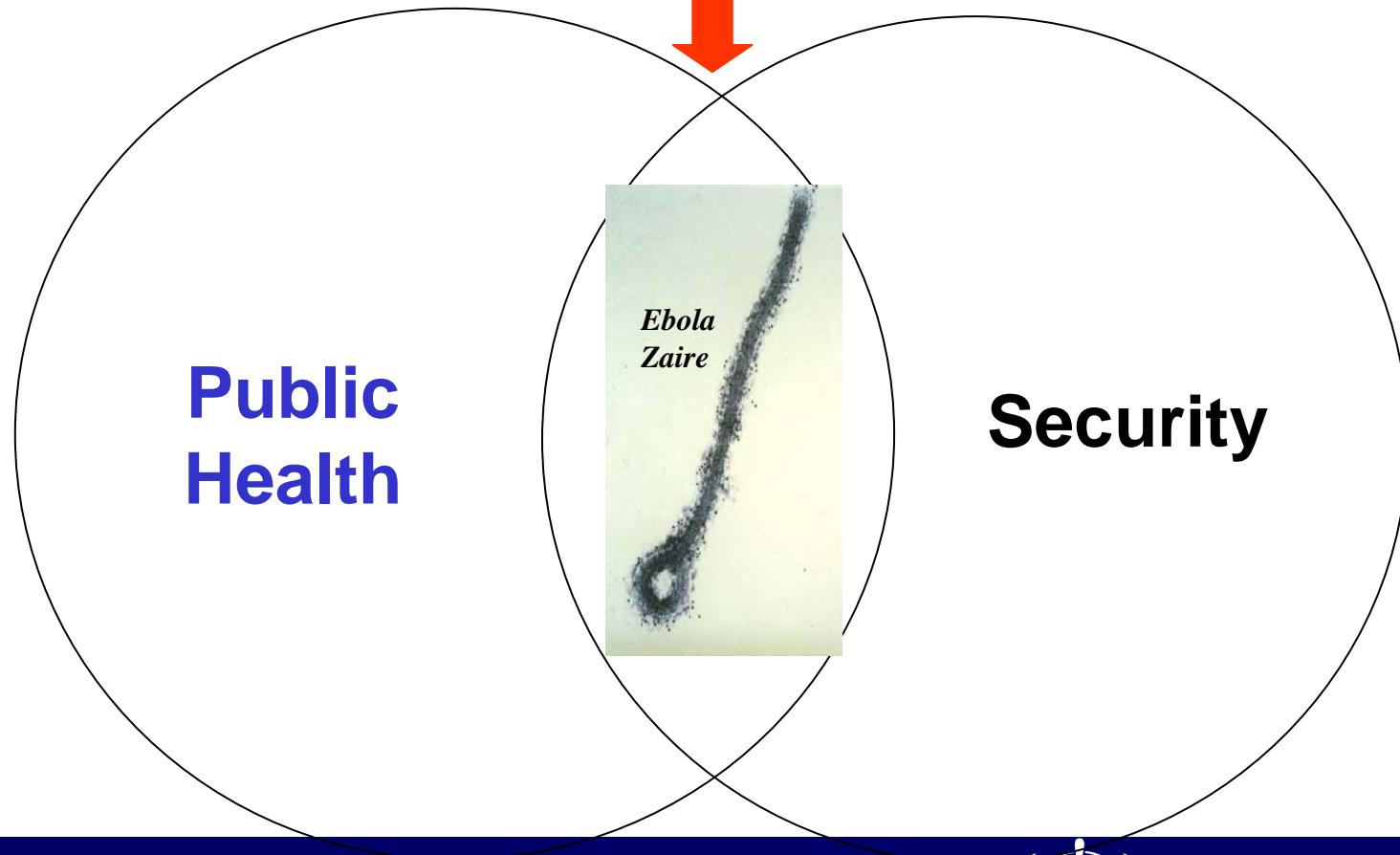
**Public Health  
issues**



**Security  
issues**

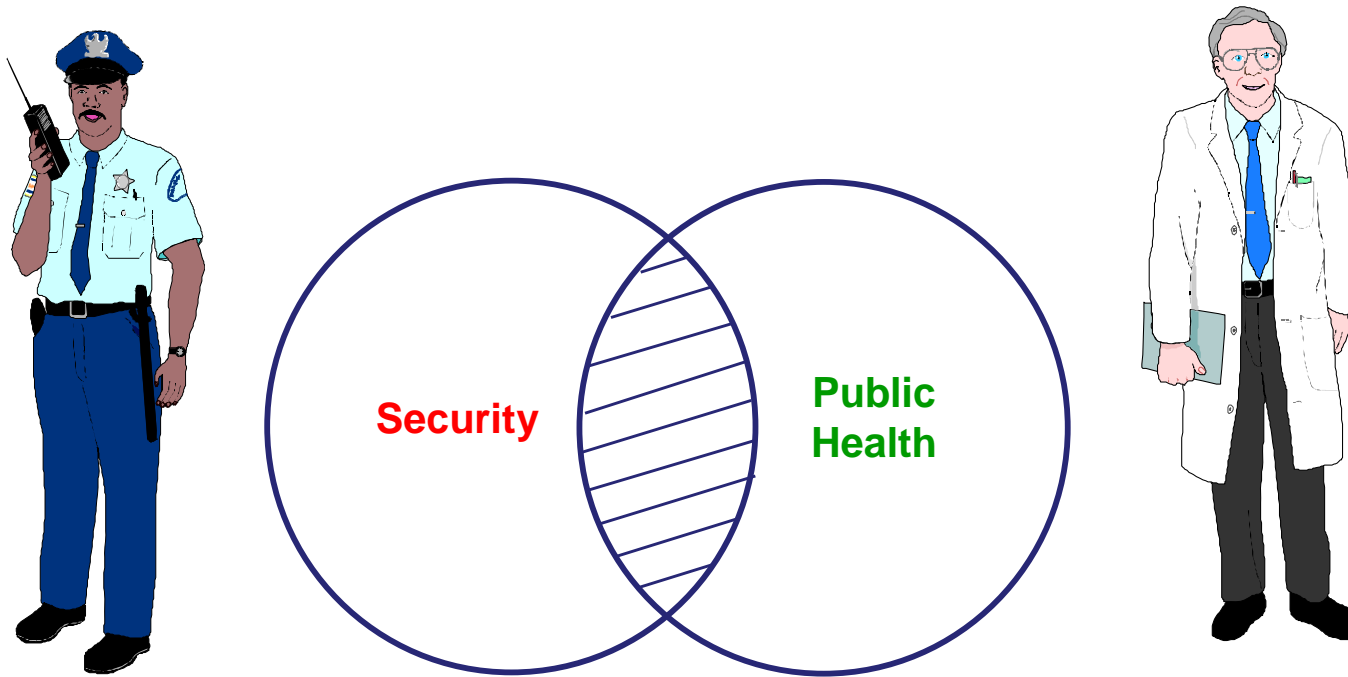
# Challenges to health and security

Intentional misuse of  
biological agent



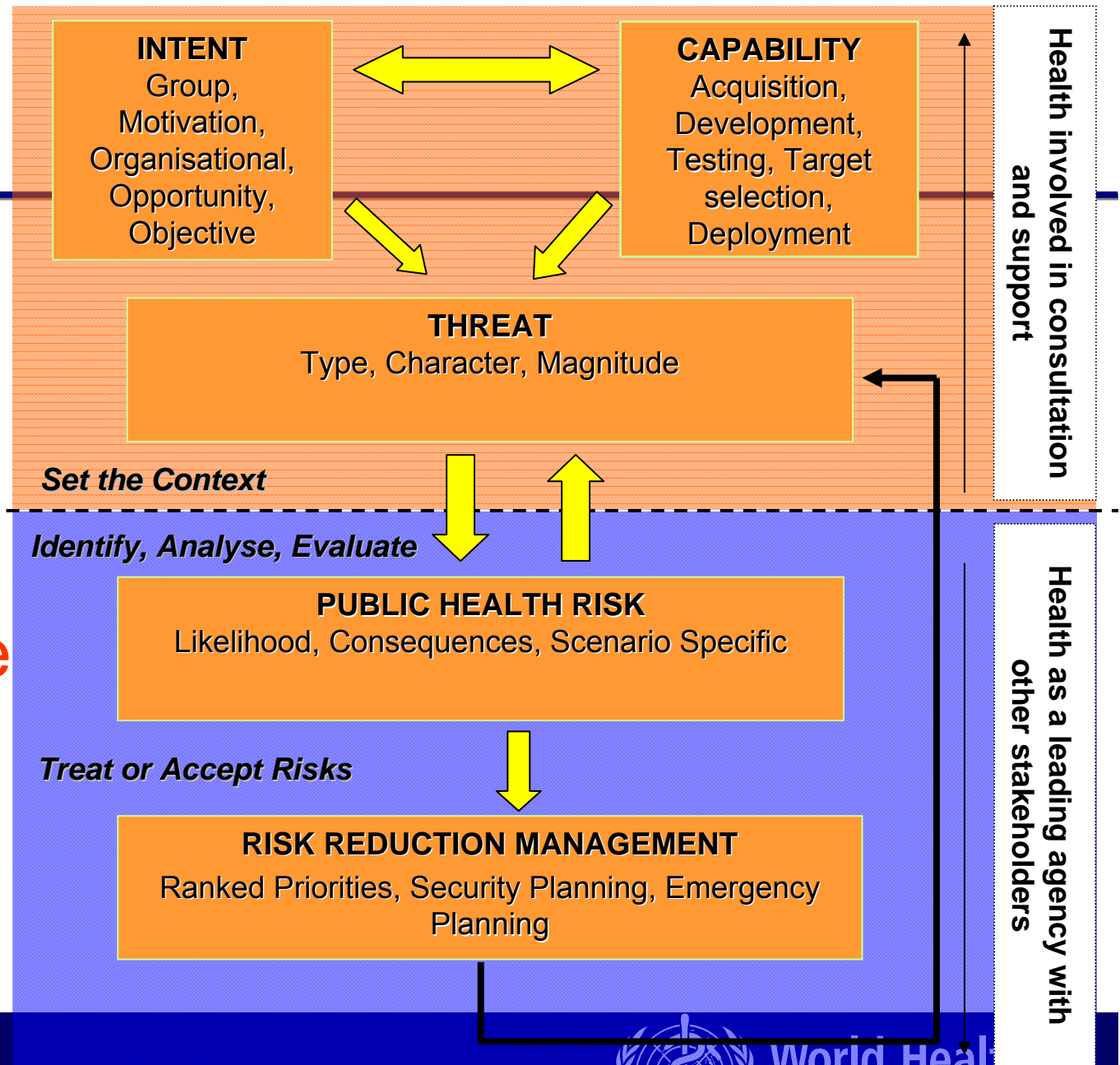
# Deliberate Use of Biological Agents represents a challenge to both Public Health and Security

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**Different roles and responsibilities,  
different mandates**

# Guidelines for Assessing National Health Preparedness Programmes for the Deliberate Use of Biological and Chemical Agents



# Combined Strength of Biosecurity and Biosafety

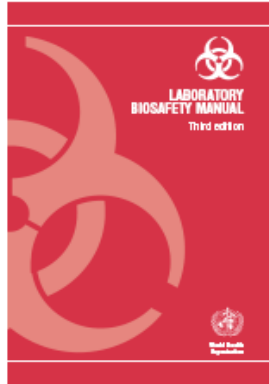
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- Laboratory biosecurity and biosafety work together to keep dangerous biological materials safe and secure in the laboratory
- Biosafety is the foundation for biosecurity
  - Biosafety is sufficient for certain risks
  - Biosafety needs to be augmented for unique higher risks



# Available guidelines and guidance documents

EN  
FR  
SP  
PO  
CH  
RU  
IT  
PE



**Laboratory biosafety (working safely)** describes containment principles, technologies and practices implemented to prevent unintentional exposure to pathogens and toxins, or their accidental release. (*Laboratory biosafety manual, 3<sup>rd</sup> edition, 2004*)

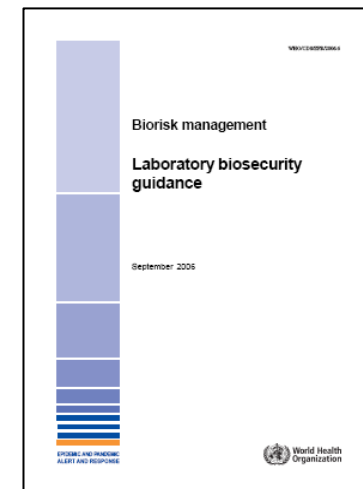
[http://www.who.int/csr/resources/publications/biosafety/WHO\\_CDS\\_CSR\\_LYO\\_2004\\_11/en/](http://www.who.int/csr/resources/publications/biosafety/WHO_CDS_CSR_LYO_2004_11/en/)

## **Laboratory biosecurity as a complement to laboratory biosafety**

**Laboratory biosecurity (keeping the work safe)** 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.

(*Biorisk management: laboratory biosecurity guidance, 2006*)

[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)



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# Laboratory biosecurity

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- Restrict the biosecurity scope to laboratory environments
- Biosafety is the basis for laboratory biosecurity
- Valuable biological materials (VBM)
- Control issues with VBM
- Access to VBM by many constituencies is necessary

# valuable biological materials (VBM)

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Biological materials that require (according to their owners, users, custodians, caretakers or regulators) administrative oversight, control, accountability, and specific protective and monitoring measures in laboratories to protect their economic and historical (archival) value, and/or the population from their potential to cause harm.



# Components of Biosecurity

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- Risk Assessment
- Physical security system
- Personnel Management
- Material Control and Accountability (MCA)
- Information security
- Transport Security
- Managing the Biosecurity Program



# Transport of infectious substances

## Biosafety:

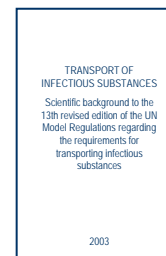
To promote the use of safe practices in the handling of pathogenic microorganisms

- in the laboratory
- **during transportation**
- in field investigations
- in manufacturing facilities
- in health-care facilities



## • Transport of Infectious Substances

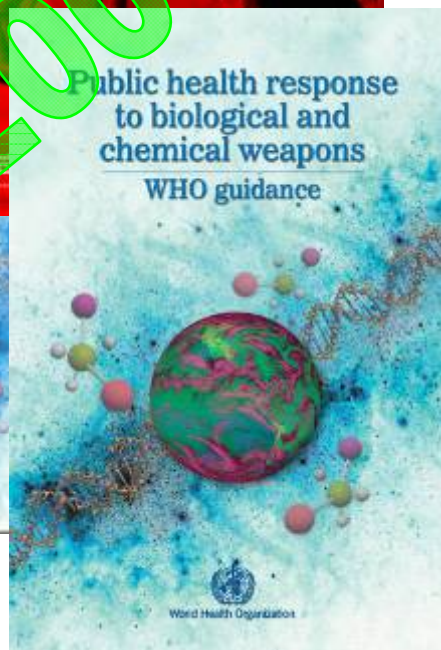
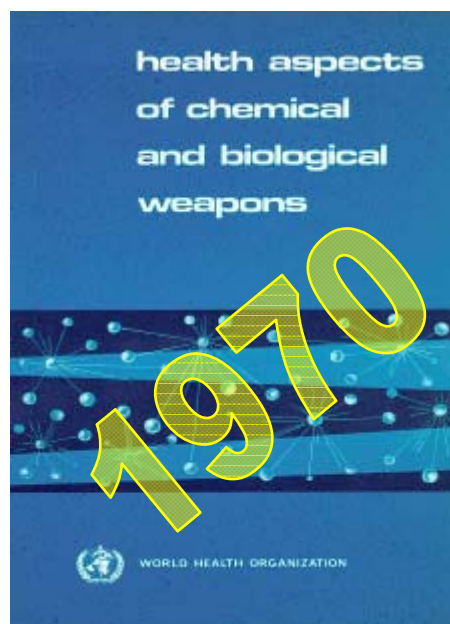
UNCETDG → ICAO → IATA



WHO 2007



## 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** being finalized*

# Disease specific (selected BW agents, 2nd ed. WHO publication)

## BACTERIA

- Anthrax
- Brucellosis
- Glanders
- Melioidosis
- Tularaemia
- Plague
- Q Fever
- Typhus Fever

## FUNGI

- Coccidioidomycosis

## VIRUSES

- Venezuelan equine encephalomyelitis
- Smallpox

## ACTIVITIES (e.g. anthrax)

- Global network of anthrax experts and laboratories
- Standard and dissemination of information
- Training and quality assurance



Epidemic Alert and Response	
World Health Organization Communicable Disease Surveillance and Response Global Alert and Response	
Disease-Specific Networks: Anthrax Questionnaire for Laboratories	
1. Contact details	
Name of laboratory	
Address	
City	Post code
Country	
Telephone	Fax
Email	Web site
Director of the laboratory	
Title (Mr, Dr, Ms, Mrs, Miss)	
Telephone	Fax
Person responsible for anthrax activities	
Title (Mr, Dr, Ms, Mrs, Miss)	
Telephone	Fax
2. Your laboratory is affiliated to:	
<input type="checkbox"/> Ministry of Health	
<input type="checkbox"/> Ministry of Agriculture	
<input type="checkbox"/> Other (specify (please specify))	
<input type="checkbox"/> University	
<input type="checkbox"/> Private laboratory	
<input type="checkbox"/> Other (please specify)	

Epidemic Alert and Response	
World Health Organization Global Alert and Response Communicable Disease Surveillance and Response	
Disease-Specific Networks: Anthrax Questionnaire for Laboratories	
1. Contact details	
Name of laboratory	
Address	
City	Post code
Country	
Telephone	Fax
Email	Web site
Director of the laboratory	
Title (Mr, Dr, Ms, Mrs, Miss)	
Telephone	Fax
Person responsible for anthrax activities	
Title (Mr, Dr, Ms, Mrs, Miss)	
Telephone	Fax
2. Your laboratory is affiliated to:	
<input type="checkbox"/> Ministry of Health	
<input type="checkbox"/> Ministry of Agriculture	
<input type="checkbox"/> Other (specify (please specify))	
<input type="checkbox"/> University	
<input type="checkbox"/> Private laboratory	
<input type="checkbox"/> Other (please specify)	

**Disease-specific networks:**  
improving public health preparedness for and response to the threat of epidemics

**Mission statement**  
To strengthen global disease-specific networks of experts and laboratories able to provide technical support to response activities in Member States, particularly developing countries, relative to the natural occurrence, accidental release, or deliberate use of biological agents that affect health.

World Health Organization  
Global Alert and Response  
Communicable Disease Surveillance and Response



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# Life Science research and global health security

## PUBLICATION

World Health Organization. Life science research: opportunities and risks for public health. Mapping the issues. WHO/CDS/CSR/LYO/2005.20. Geneva, World Health Organization, 2005.

# Responsible use of life science research

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Dual use research

Responsible use of science

Research management

Laboratory biosafety and laboratory biosecurity

# The implications of life science R&D for global health security

## The importance of a public health perspective

- Life science R&D can have both **benefits and risks** for public health.
- **Control mechanisms** for managing the risks could **hinder further development**.
- Strong **public confidence** must be maintained in science, and **scientific advice for policymaking** must be supported.
- The levels of **information and experience vary among WHO Member States**.



# Bio-Risks from dual use

- *Molecular biology biotechnology and genetic engineering*
- *Dual use nature of Biotechnology*
- *Low probability, high consequence*





# OBJECTIVES

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To raise awareness among WHO Member States about the implications life science research have for global health security and to safeguard the public health benefits of life science research for global health security through:

- Engaging dialogue with WHO Member States, international organizations and other interested communities (e.g. life science communities and private sector);
- Gathering and providing information on these issues from a public health perspective;
- Promotion of ethical and responsible life science research (codes of conduct?);
- Providing international guidance and technical support for Member States, particularly in developing countries, to address such issues in a manner that will safeguard the public health benefits of life science research and development.

# ACTIVITIES

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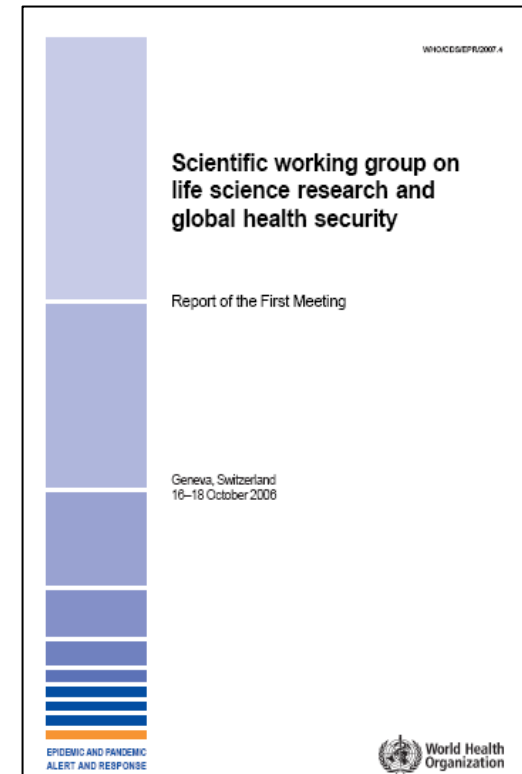
Establishment of a network of experts and collaboration with international organizations and other interested partners;

- Production of working papers covering different aspects of the project;
- Organization and coordination of meetings of the scientific working group on "Life science research and global health security" (16-18 October 2006, Geneva and December 2007 Bangkok);
- Organization and coordination of an electronic platform;
- Organization of regional workshops;
- Provision of advice and support to countries and other partners;
- Preparation of scientific working group reports for comments and publication of a guidance document.

# Scientific Working Group (2006)

## 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, laboratories and research





# *GLaDNet*

Global Laboratory  
Directory  
of Networks

Supporting effective  
preparedness and  
timely response to  
diseases of  
epidemic/pandemic  
potential and emerging  
disease threats.

Connecting laboratory  
networks as global  
partners



**Epidemic and Pandemic Alert and Response**

# GLaDNet STRATEGIC GOALS AND OBJECTIVES

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Establish **global connectivity** and **transparency** among laboratories

Enhance **preparedness** for timely responses to local, regional and global events

Promote means to **access ("share")** laboratory capacity globally

Foster an environment that encourages **information sharing** and promotes **team building** and **collaboration** between networks and laboratories

## Building the Network Directory, brick by brick

*GLaDNet is the "mortar" part of the wall*

- Get to “know your neighbors” in advance of event response
- Harmonization of basic operations (protocols, logistics, communication)
- Serve to implement International Health Regulations

Acad  
inst

WHO

Private lab

International  
reference lab

Expert

# In conclusion

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WHO Biorisk Reduction Management Activities include:

- Guidelines/recommendations, BS/BSc/LS/Tra/Del
- Awareness workshops for Health authorities, policy makers, Health regulators
- Training courses for laboratory managers and experts
- Train the trainers/Biosafety officers
- Biorisk reduction curricula for under/post graduates/Biosafety professionals
- Risk Assessment/checklist
- Connectivity/communication

Accidental release

Natural infection

Deliberate use

**Biorisk Reduction Management**



# I wish you a healthy, safe and secure world

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## Thank you



[mohammadia@who.int](mailto:mohammadia@who.int)

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SECURITY



World Health  
Organization