Workshop on trade monitoring for biological dual use items, 17-18 April, Brussels, Belgium

International Health Security, Dual use issues and WHO's Strategies

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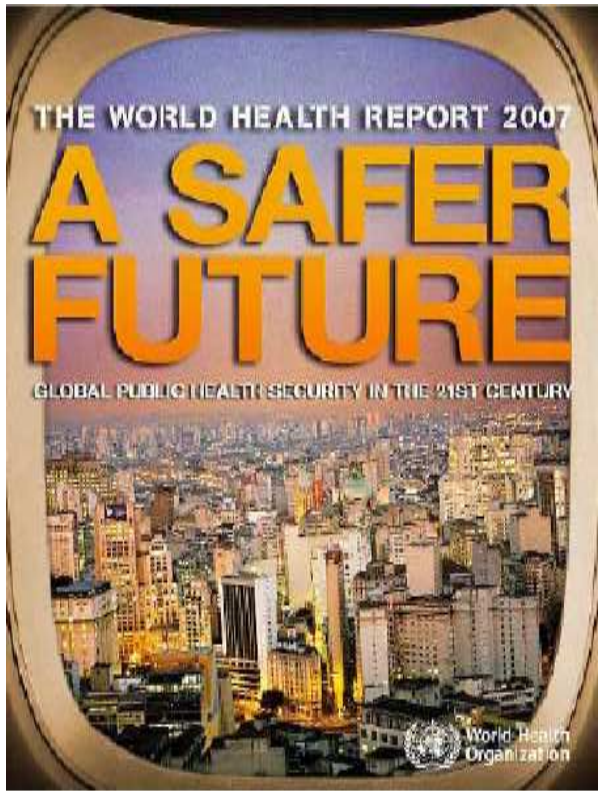
Lessons from the 2007 WHO World Health Report:

"Global Public Health Security - A Safer Future"



Global public health security – a definition

"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

. 685 verified events of international public health concern occurred from September 2003 to September 2006 (a mean of about 5 events 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* http://www.who.int/whr/2007/en/index.ht

Spectrum of Microbial Threats

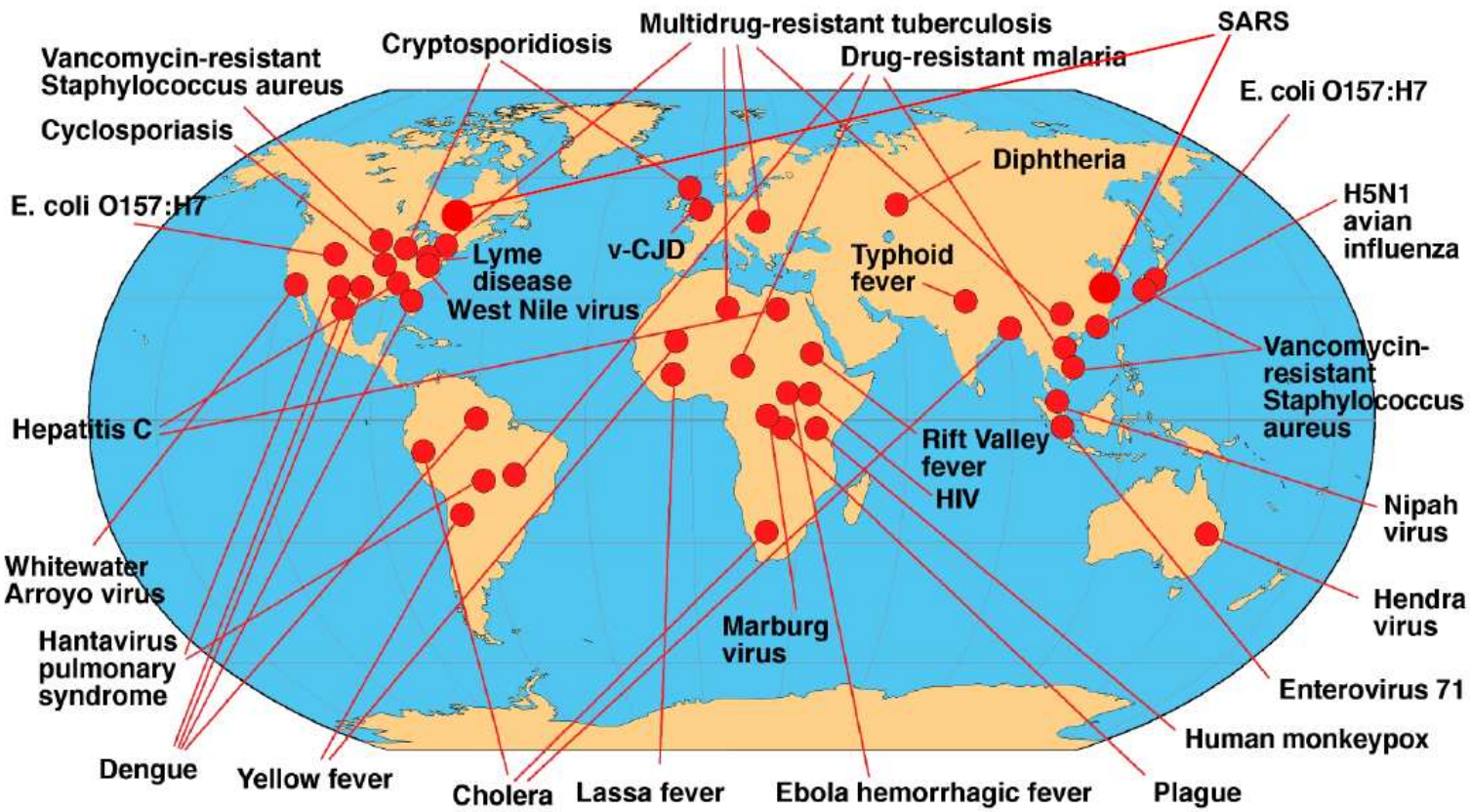
- Newly recognized pathogens
- New geographical spread
- Resurgence of endemic infections
- Antimicrobial-resistant infections
- Infectious etiology of chronic diseases
- Intentional use of biological agents

Leading Infectious Causes of Death Worldwide

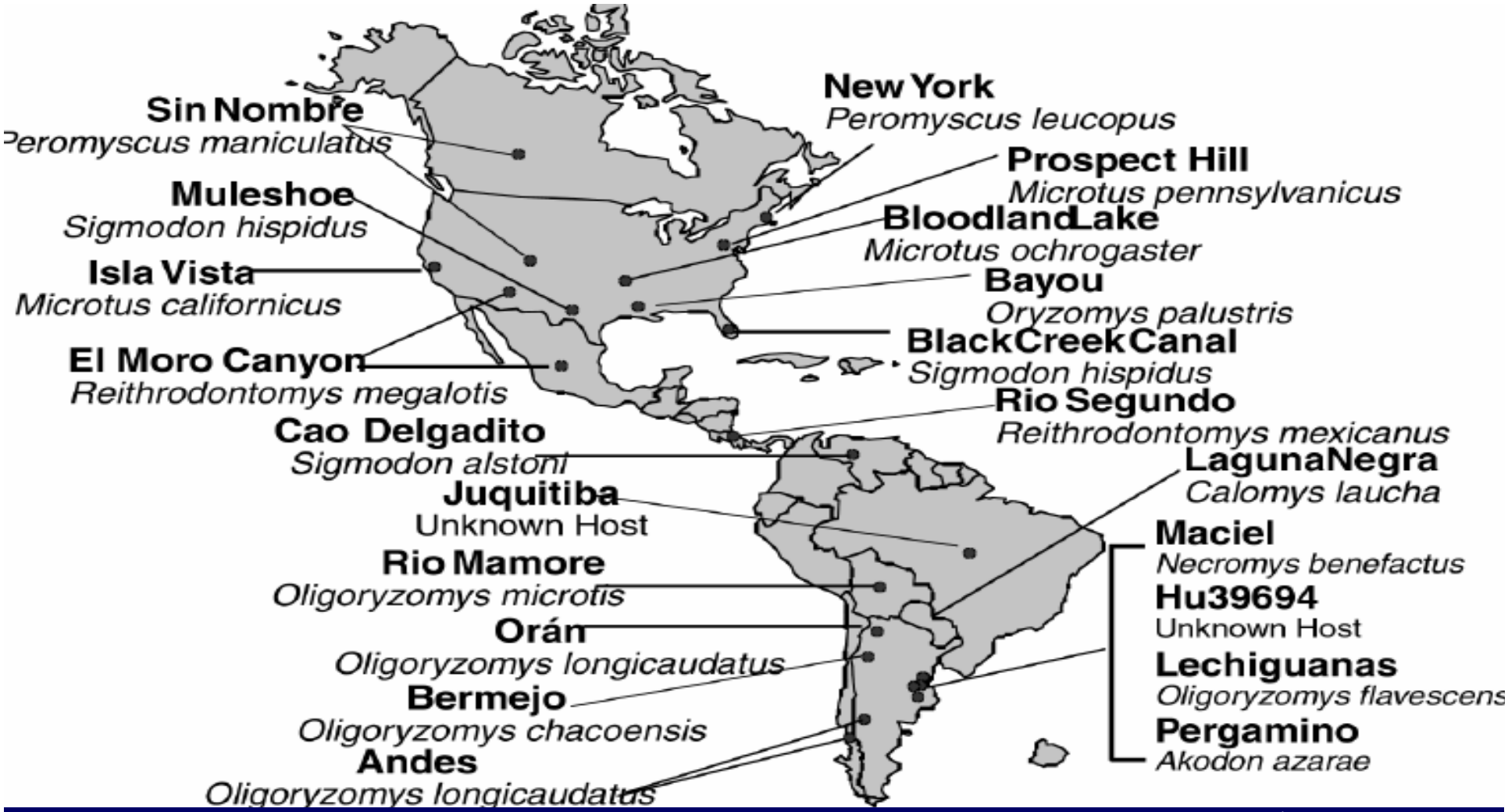
Cause	Rank	Number of Deaths
Respiratory infections	1	3,871,000
HIV/AIDS	2	2,866,000
Diarrhoeal diseases	3	2,001,000
Tuberculosis	4	1,644,000
Malaria	5	1,124,000
Measles	6	745,000
Pertussis	7	285,000
Tetanus	8	282,000
Meningitis	9	173,000
Syphilis	10	167,000

Source: WHO, 2002

Recent Microbial Threats



New World Hantavirus



Factors in Emergence (1)

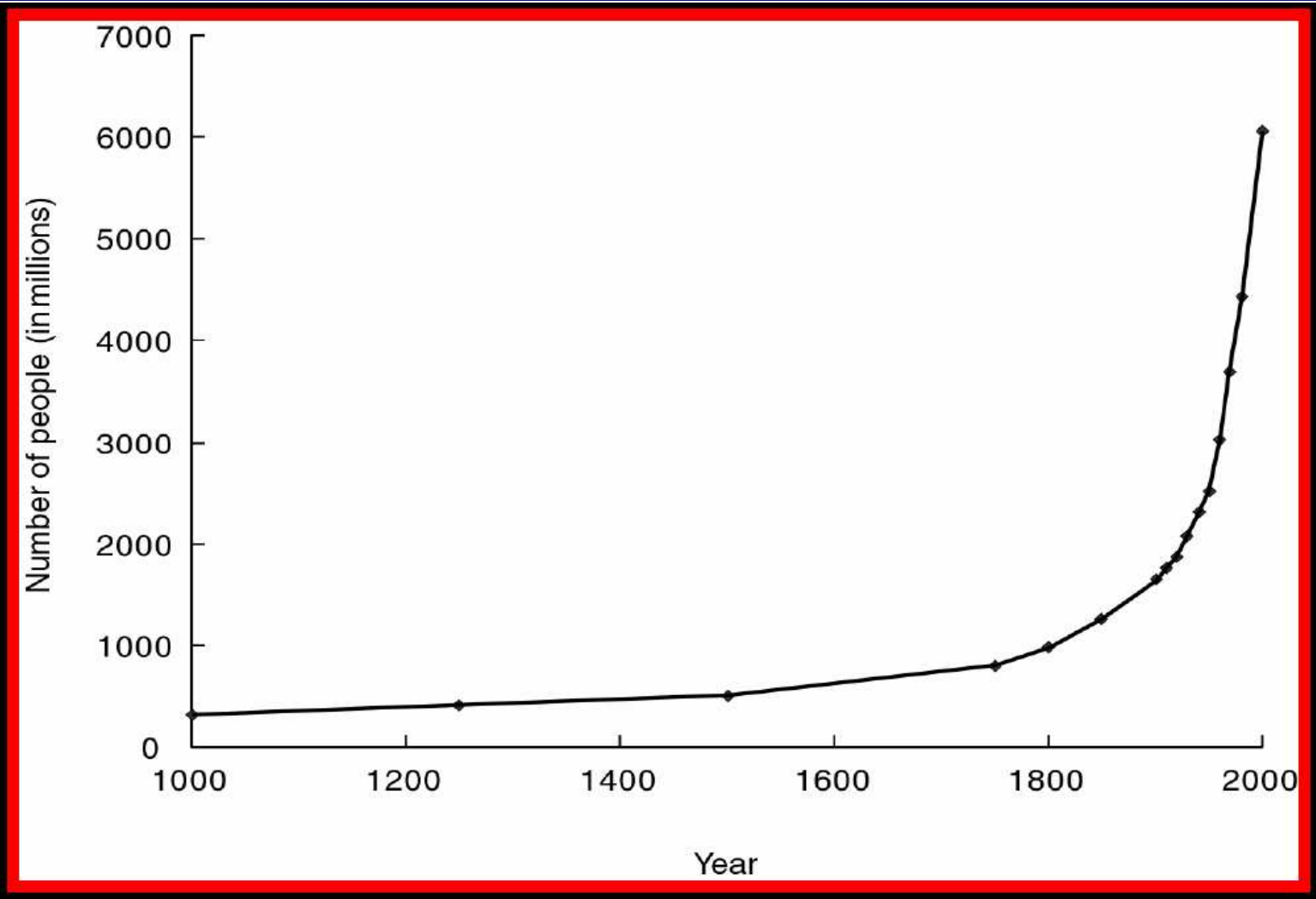
- Human demographics and behavior
- Technology and industry
- Economic development and land use
- International travel and commerce
- Microbial adaptation and resistance
- Breakdown of public health measures

Factors in Emergence (2)

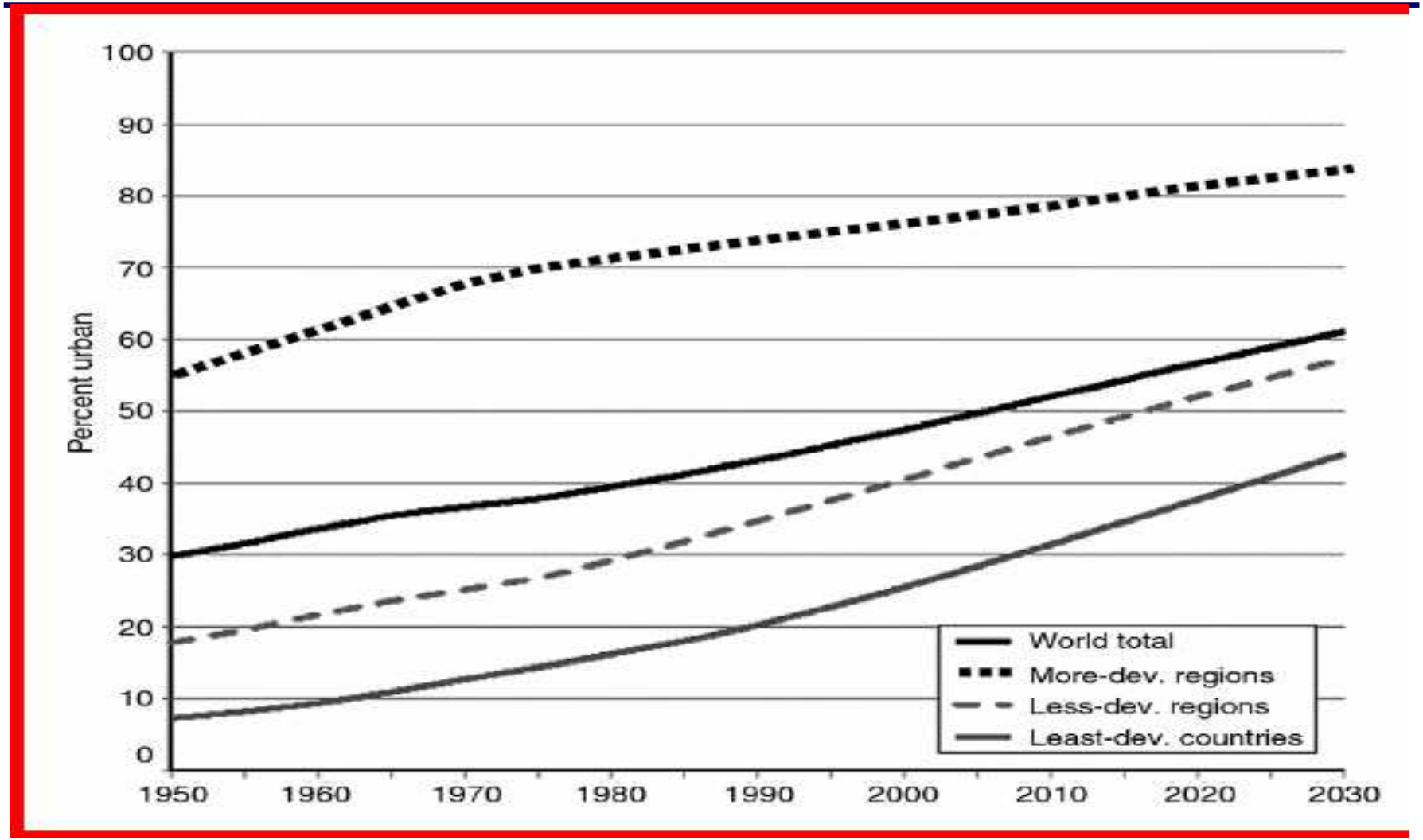
- Human susceptibility to infection
- Climate change
- Changing ecosystems
- Poverty and social inequality
- War and famine
- Lack of political will and understanding
- Intent to cause harm

The Human Population Explosion

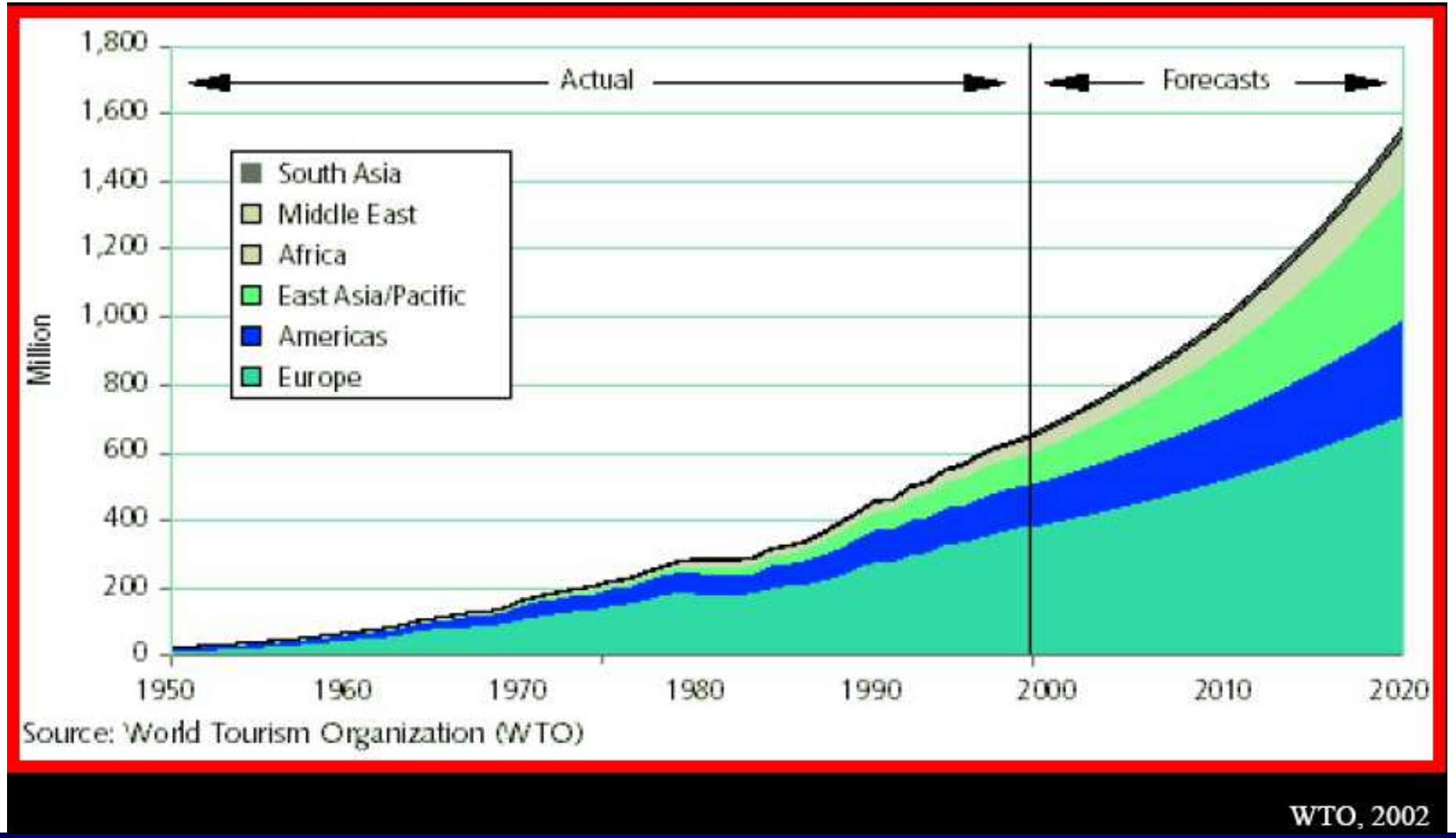
Source: UN, 1999



World Urbanization Trends

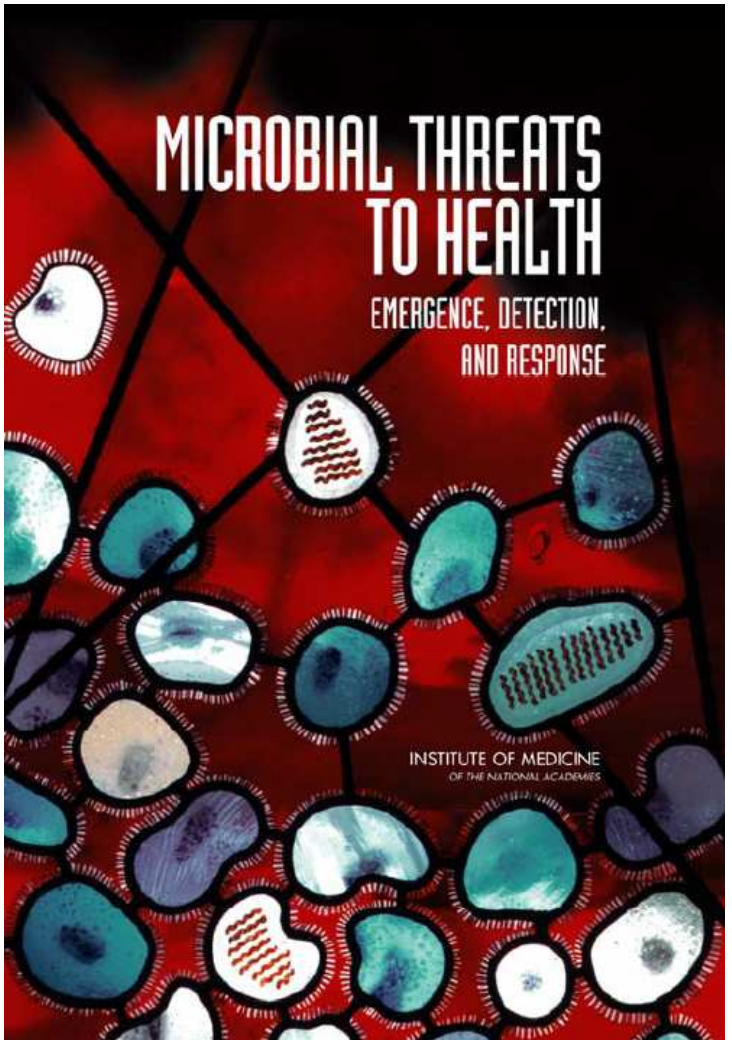


International Tourists Arrivals



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.



Action Plan

Improve global surveillance and response

Enhance domestic public health capacity

Improve disease reporting

Improve vector-born disease control

Develop and use of new diagnostic tools

Support vaccine and antimicrobial production

Educate and train health workers

Develop comprehensive research agenda

Explore innovative health information technology

Bioterrorism issues

Bio-science can be misused to develop bio-weapon

Simple to produce

Cheap to acquire

Easy to use

However, a tool for panic not a reality

States have obligations

Terrorist groups are more interested

Bio-Risks from deliberate use

Molecular biology biotechnology and genetic engineering

Dual use nature of Biotechnology

Low probability, high consequence

Natural VS deliberate outbreaks

Since 11 September 2001,

5 persons are thought to have died from deliberate contamination with Anthrax – No high technology was involved

None in Europe

In the same period over 20 million people died from AIDS, TB and Malaria

Altogether natural infections probably killed over 100 million world-wide

Many diseases are as yet unrecognised infections - cancers caused by viruses, heart disease (caused by *Chlamydia pneumoniae)* and mental illnesses

Impacts of control measures on public health systems

Research programmes

Vaccine production

Diagnosis of epidemic and pandemic diseases

Information sharing

Transfer and transport of materials and samples

BWC protocol

ANNEXES

A. DECLARATIONS

I. DEFINITIONS

II. LISTS AND CRITERIA (AGENTS AND TOXINS)

III. LIST OF EQUIPMENT

IV. THRESHOLDS

V. PROGRAMMES AND FACILITIES

VI. DECLARATION FORMATS

LISTS OF AGENTS AND TOXINS
Human and zoonotic pathogens

Viruses	
1.	Crimean-Congo haemorrhagic fever
2.	Eastern equine encephalitis virus
3.	Ebola virus
4.	Sin Nombre virus
5.	Junin virus
6.	Lassa fever virus
7.	Machupo virus
8.	Marburg virus
9.	Rift Valley fever virus
10.	Tick-borne encephalitis virus
11.	Variola major virus (Smallpox virus)
12.	Venezuelan equine encephalitis virus
13.	Western equine encephalitis virus
14.	Yellow fever virus
15.	Monkeypox virus

Bacteria	
1.	Bacillus anthracis
2.	Brucella melitensis
3.	Brucella suis
4.	Burkholderia mallei
5.	Burkholderia pseudomallei
6.	Francisella tularensis
7.	Yersinia pestis
8.	Coxiella burnetii
9.	Rickettsia prowazekii
10.	Rickettsia rickettsii

LIST OF EQUIPMENT

- Each State Party shall supply all the information required concerning equipment specified in Annex A which is present at or used in a facility declared in accordance with Article 4 (6), (8) to (14) and Appendices C and D.

- The list of equipment specified in Annex A may also be used in accordance with Annex B (159) and (160).

- Review of, and amendment to, the list shall be conducted in accordance with Article 21 (4) and (5).

Types of dual use equipment

Aerobiology

Fermentation

Fixing/drying

Incubation

Separation

Formulation

Finishing

Filling

Definition:

Any equipment used in the process of biological research and production which may also be used for prohibited purposes

NB. Almost all items being used in the biological research, diagnosis and production are of dual use nature

Some dual use equipment

Aerobiology equipment:

Aerosol chambers (either static, dynamic, explosive)

Equipment designed or utilised to generate aerosols of micro-organisms or toxins and simulants

Aerosol analytical equipment to determine the size of aerosol particle

___ Not Present

___ Present

___ Utilised

___ Utilised in high biological containment

___ Utilised in maximum biological containment

Fermentation equipment:

Types of fermenters:

Aerobic/Anaerobic

Bacterial/viral/yeasts

Glass/steel

Lab scale/mass production

Containment, BWC list:

Indicate the presence, utilisation and containment usage of the following equipment at the declared facility:

(a) Fermenter(s)/bioreactor(s) with total/internal volume exceeding 50 litres

INFORMATION TO BE PROVIDED IN THE DECLARATIONS REQUIRED UNDER ARTICLE 14 (33)

1. A general description of measures taken to facilitate the fullest possible exchange of equipment, materials and scientific and technological information for the use of the microbial and other biological agents, and toxins for peaceful purposes.
2. A general description of measures taken to further the development and application of scientific discoveries in the field of bacteriology (biology) for the prevention of disease or for other peaceful purposes.
3. A general description of any other measure that the State Party has taken to implement Article X of the Convention and Article 14.
4. A general description of the outcome of any review undertaken on the existing national trade legislation or regulations, in accordance with Article 14 (6) (b).

How to prevent Bio-Risks of dual use

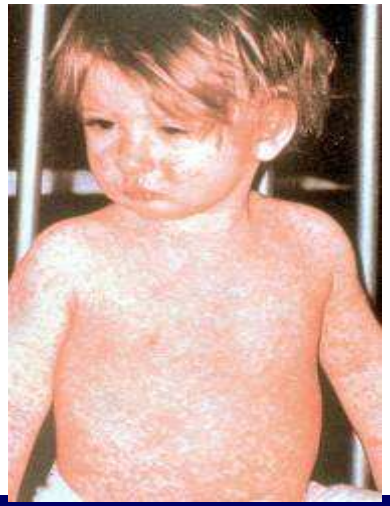
- Establish a global partnership among all relevant entities, WHO, OIE, FAO, WCO, Interpol
- Each of the above (based on their mandate) should establish or enhance response to dual use issues
- Create transparency in the global trade of dual use items
- Establish criteria to identify and monitor dual use of items
- Work with the States Parties to strengthen national monitoring on trade (export and import) of dual use items

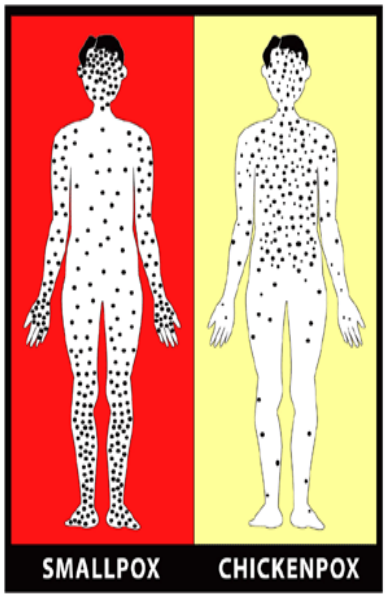
Points of entry

Points of entry provisions in the International Health Regulations (2005) are designed to minimize public health risks caused by the spread of diseases through international traffic. The IHR (2005) define a point of entry as "a passage for international entry or exit of travellers, baggage, cargo, containers, conveyances, goods and postal parcels, as well as agencies and areas providing services to them on entry or exit". There are three types of points of entry: international airports, ports and ground crossings.

Rash Identification

(Visual Inspection at the Border)





Prevention and control at border checkpoints

Imported cases:

Thermal and health screening at border checkpoints

Health declaration cards

Health alert notices

Exported cases:

Cross-border contact tracing

Working with WHO, ASEAN + 3 partners (China, Japan, S Korea)

Health Check Station for Plague at airport

Border crossing decontamination

Ships

(Cruise ship outbreak/quarantine in port)

First line of defense, border entry control

Transparency on trade of dual use items

Supplier and exporter certificate

End user certificate

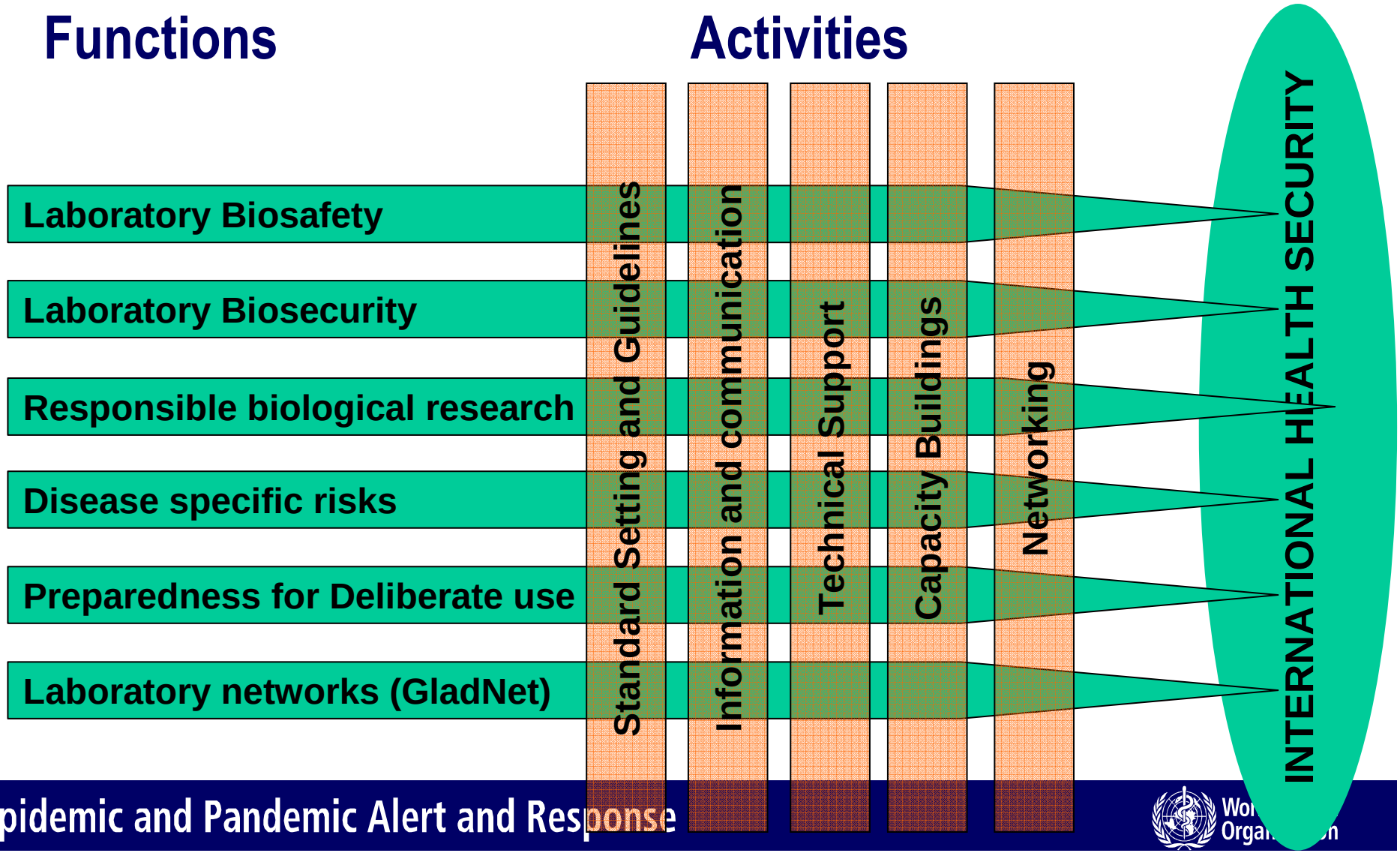
Endorsement by relevant national society/syndicate

Approval by the relvant national authority

Endorsement by the relevant (specialized) international agency

Final approval by relevant committee of WCO

WHO Biorisk Reduction Management



Preparedness for Deliberate Epidemics

Bioterrorism and public health

Natural, accidental and deliberate epidemics - WHO's role

Constitution: WHO shall ... furnish appropriate technical assistance and, in emergencies, necessary aid upon the request or acceptance of Governments

Global Health security

Global Alert and Response Operations: gathers official reports and rumors, publishes confirmed Information.

GOARN: Global outbreak and response network: governments, universities, ministries of health, other UN agencies, networks of overseas military laboratories and NGOs.

Preparedness for the unexpected "Global public health response to natural occurrence, accidental release or deliberate use of biological and chemical agents or radio nuclear material that affect health" (WHA55.16, 2002).

WHO's Legal platform

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)

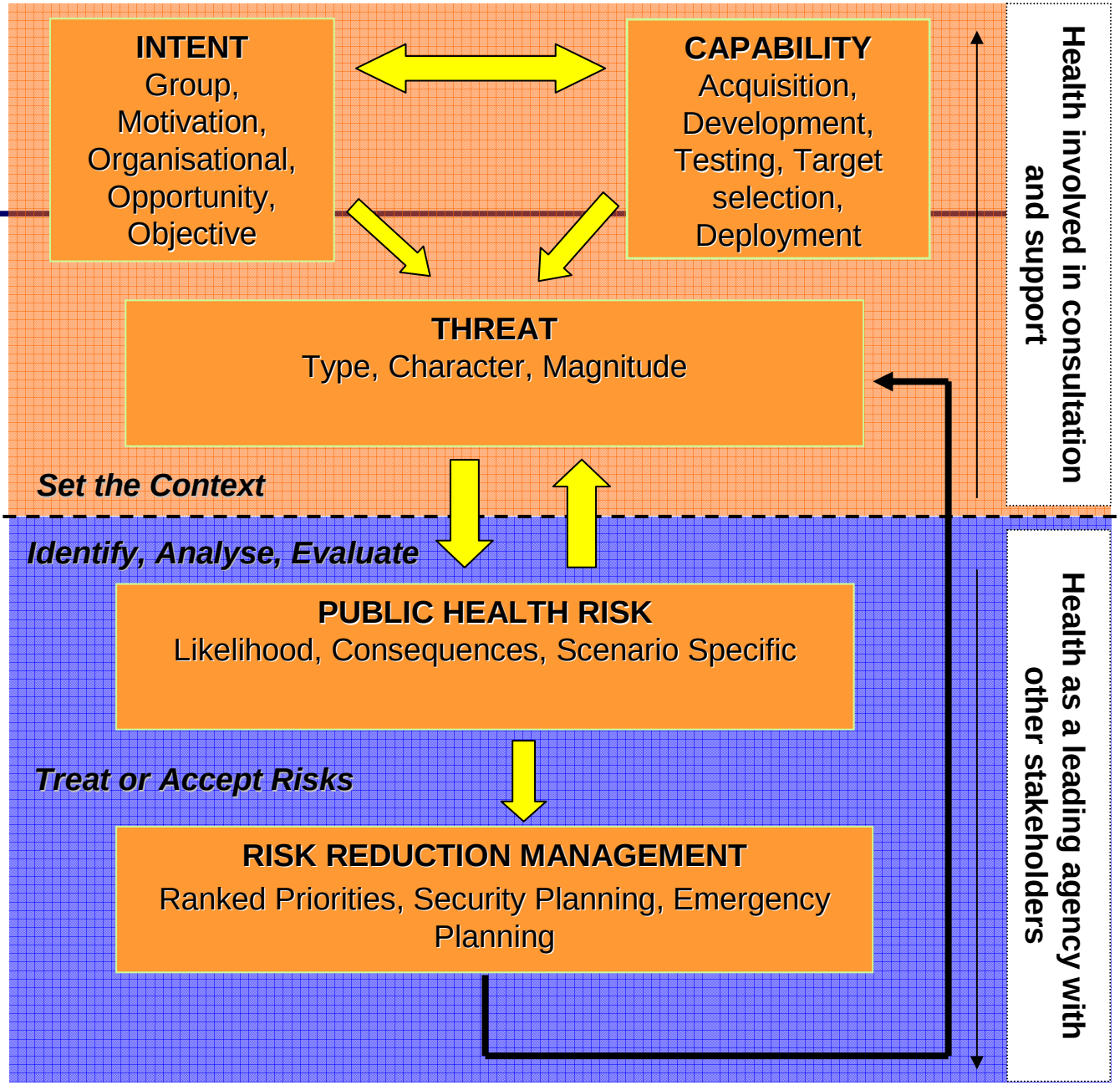
- "Resolution on Global Health Security: Epidemic Alert and Response"

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)

"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

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



Risk and Disaster

Risk X Vulnerability

Management = Disaster

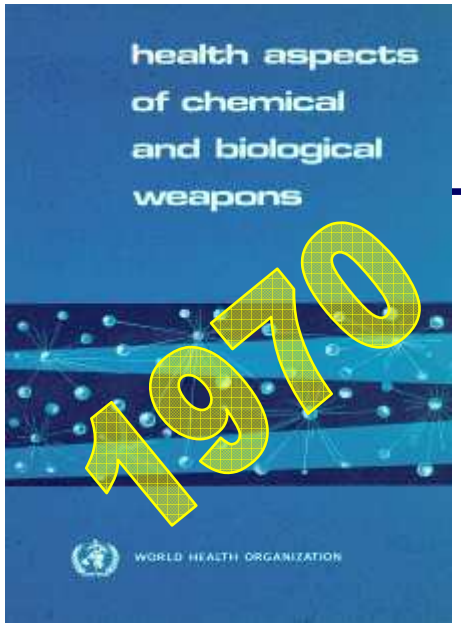
%100 X %50

%10 = %500

%100 X %10

%100 = %10

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

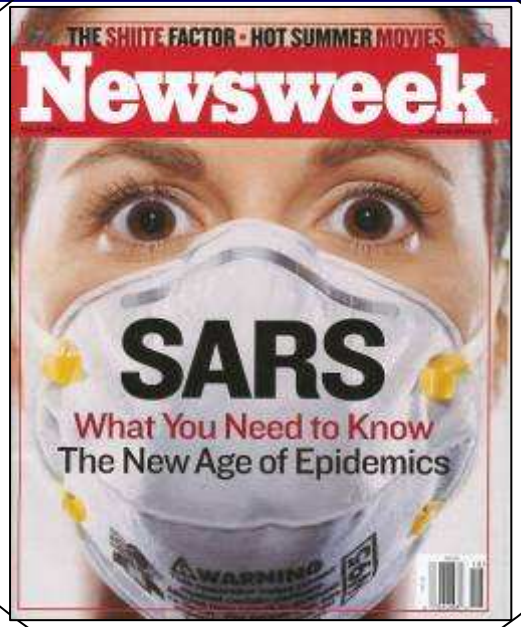
VIRUSES

- Venezuelan equine encephalomyelitis
- **Smallpox**

ACTIVITIES (e.g. anthrax)

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

Public Health and security activities have traditionally had minimal overlap

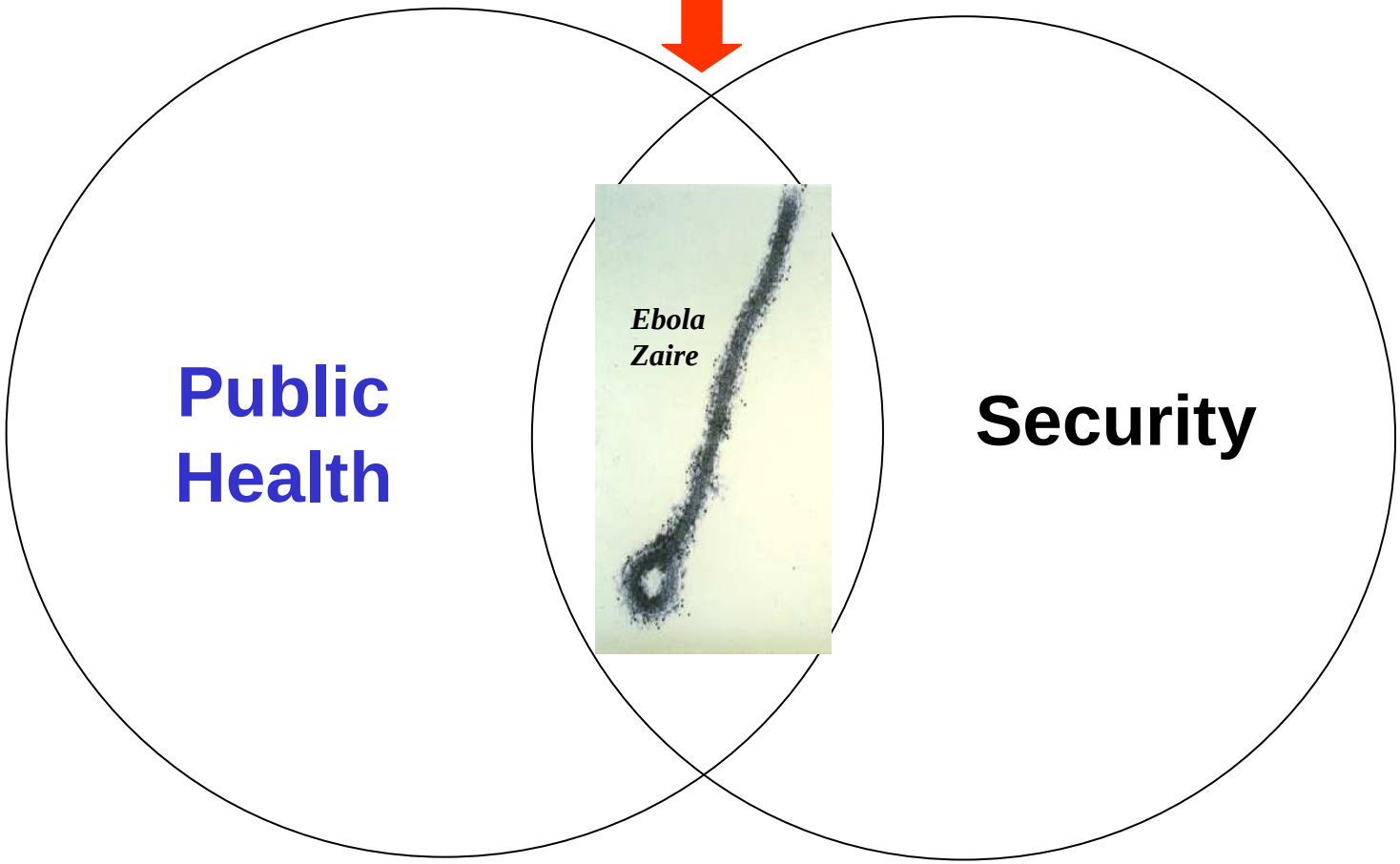


Public Health issues

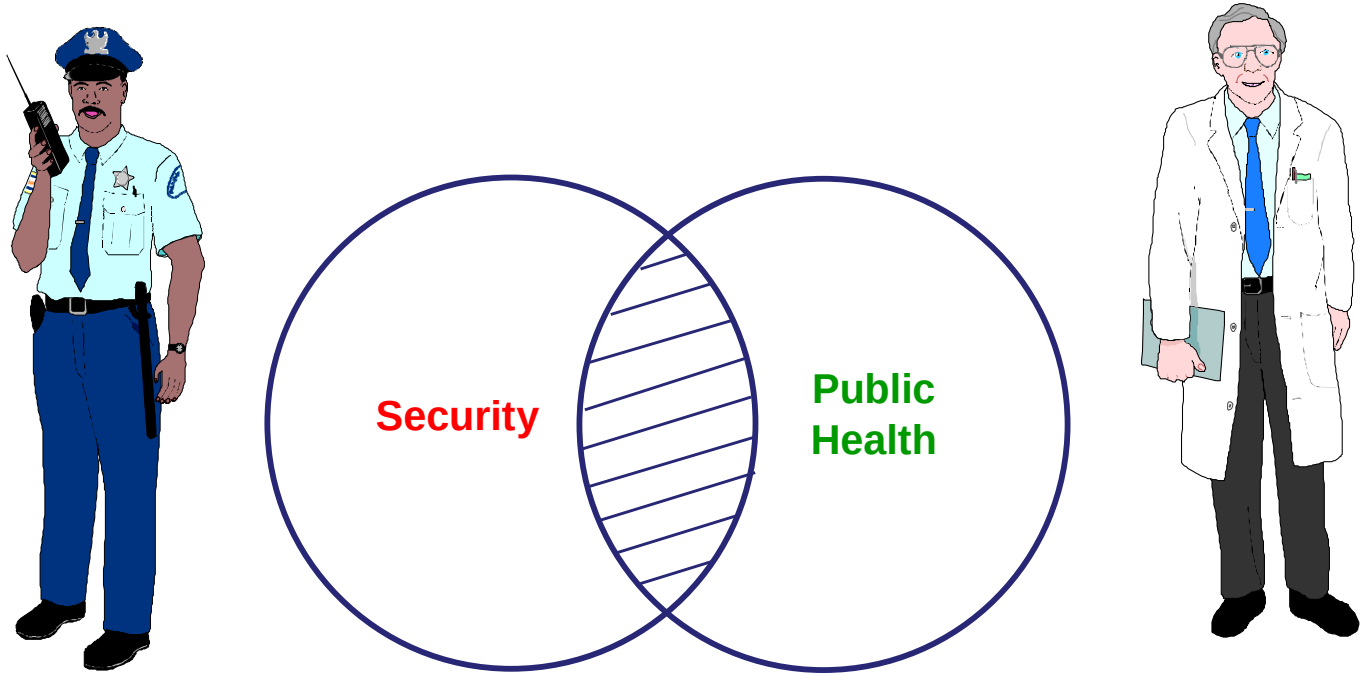
Security issues

Challenges to health and security

Intentional misuse of biological agent



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



Different roles and responsibilities,
different mandates

WHO's involvement in Biosecurity:

Preamble of the WHO Constitution of 1948 states that:

"THE STATES Parties to this Constitution declare, in conformity with the Charter of the United Nations, that the following principles are basic to the happiness, harmonious relations and security of all peoples."

Article 2(d) of the constitution also stresses that: WHO shall "... furnish appropriate technical assistance and, in emergencies, necessary aid upon the request or acceptance of Governments;…

International Health Regulations (IHR)

The International Health Regulations Approved by the WHA58 (may 2005) and intered into force 15 June 2007,is mainly targeted to "public health emergencies of international concern" and in Article 13 states that the WHO shall publish, in consultation with member states guidelines to support them in the development of capacities to respond promptly and adequately to public health risks and public health emergencies of international concern

Laboratory biosecurity

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 biosecurity guidelines**

"Laboratory biosecurity"
refers to institutional and personal security measures designed to prevent the loss, theft, misuse, diversion or intentional release of valuable biological materials (VBM) including pathogens and toxins.

Components of Bioecurity

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

Physical Security

Components of a physical security system

- Graded protection
- Access control
- Intrusion detection
- Response capability
- Training
- Performance testing

Personnel Management

Employee screening

- proportional to the roles and responsibilities of the individual
- Correlate with access authorization

Visitor control

- Casual visitors should be escorted in restricted areas
- Working visitors should be processed in the same manner as regular employees

Badges

- Identification badges should be worn in institutions that have higher risk pathogens and toxins
- Badges should be returned upon termination of access

Material Control and Accountability (MCA)

Identify what materials to control

- Identify pathogens and toxins of concern

Identify how will materials be controlled

- Containment
- Procedures such as inventory and location of use

Identify who is accountable for the materials

- All material should have an “accountable person”

Identify where is MCA applicable

- In laboratories
- In Culture Collection Centers
- During transport

Managing the Biosecurity Program

Role of management to ensure biosecurity programme is:

- Appropriate to need (based on facility risk assessment)
- Resourced and cost-efficient for risk
- Graded in protection activities
- Coordinated with biosafety, good lab practices, security community, etc
- Define roles and responsibilities in written plan
- Provide regular training
- Provide routine system assessments
- Biosecurity plan is corrected/modified as needed

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.

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**.

The Economist

OBJECTIVES

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

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.**

WHO Biosafety programme

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

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

Smallpox: 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:

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:

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.

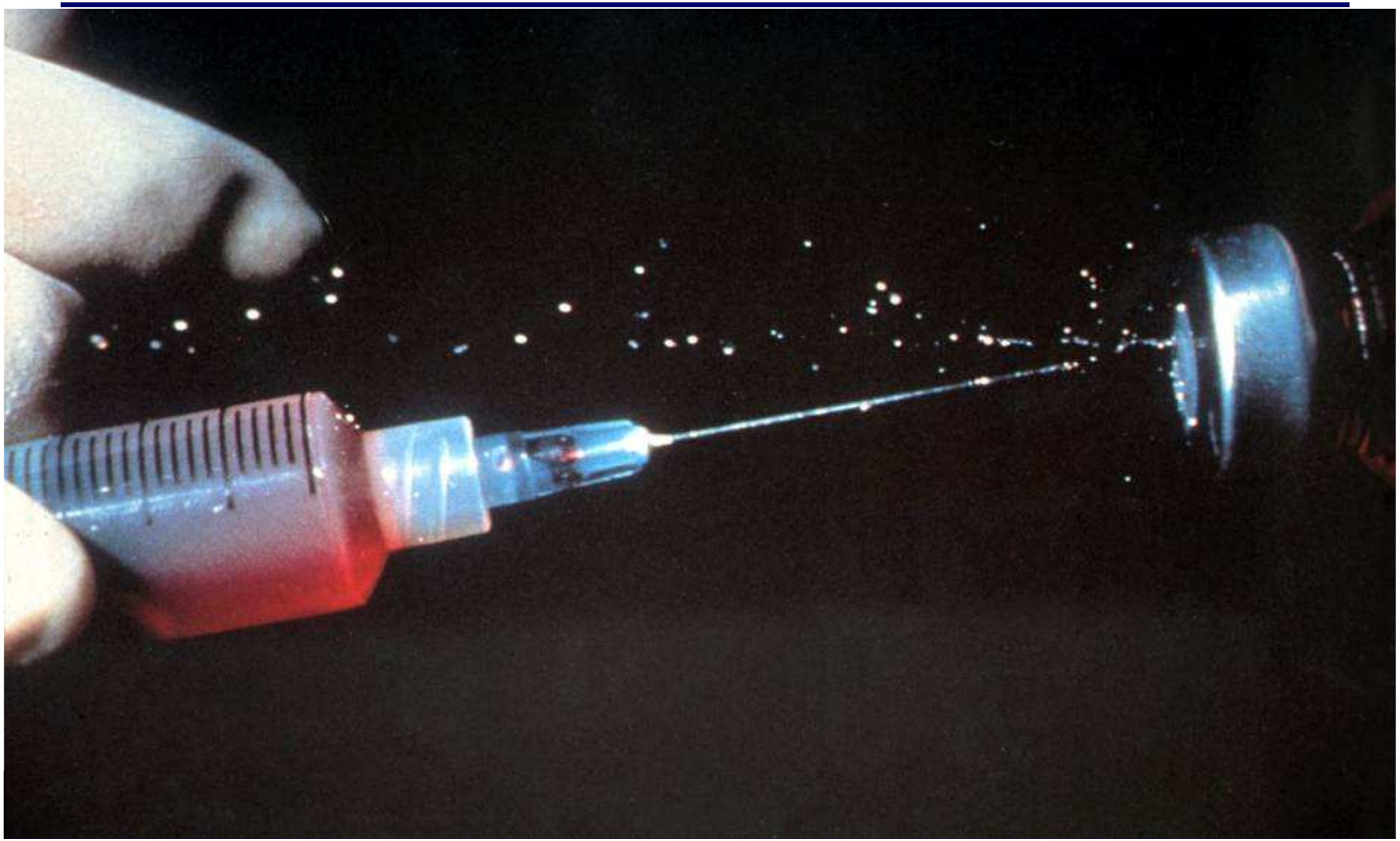

MICROFLOW


StenlCARD III

Epidemic and Pandemic Alert and Response

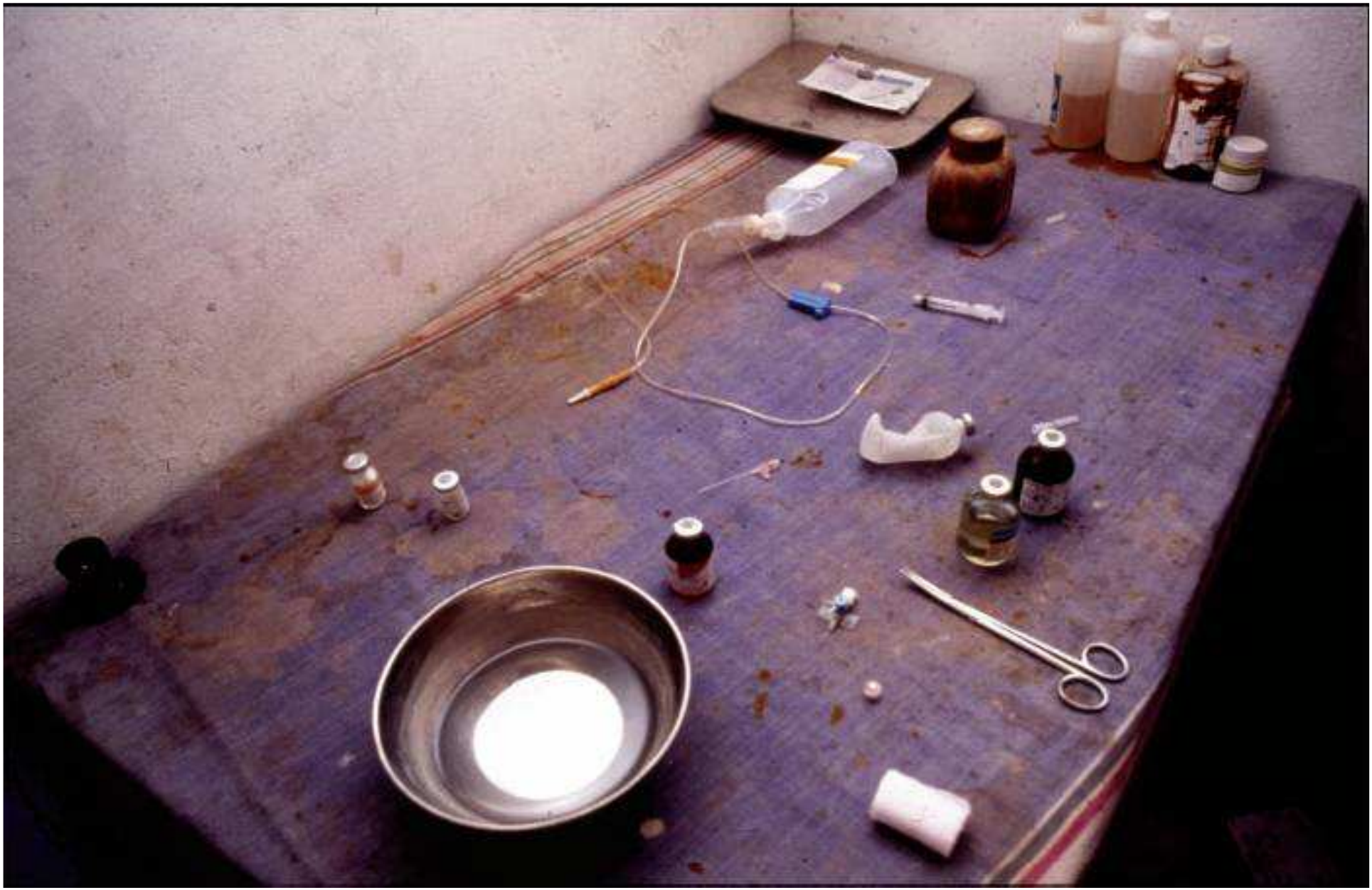
World Health Organization

Withdrawing Syringe from Vaccine-Stoppered Bottle



Epidemic and

World Health Organization



Epidemic and Pandemic Alert and Response (EPR)

Crimean Congo Haemorrhagic Fever (CCHF)

World Health Organization


15

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**

WHA58.29 urges Member States to

- review the safety of their laboratories and their ... protocols
- promote biosafety laboratory practices for ... handling and transport;
- enhance compliance of labor... biosafety guidelines
- minimize the possibility ... laboratory acquired infections and resultant spread ... community
- facilitate acc... and containment devices
- develop ... training programmes

Member States agreed to strengthen biosafety

WHA58.29 requests the Director General to:

- ensure WHO's active role in improving l
- support other programmes and p g laboratory biosafety
- support sharing of bios d experience among Member States
- consult M velopment of WHO guidelines and manu
- provide port for strengthening biosafety
- Report reg to the EB on implementation of resolution

WHO is requested to support global biosafety strengthening

Personal Protective Equipment (PPE)

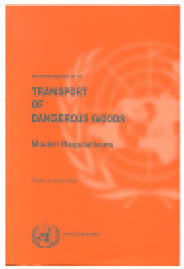
Transport of infectious substances

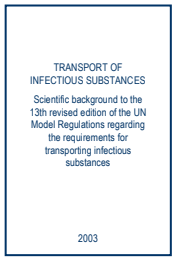
Biosafety:
To promote the use of safe practices in the handling of pathogenic microorganisms

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

- **Transport of Infectious Substances**

UNCETDG → ICAO → IATA



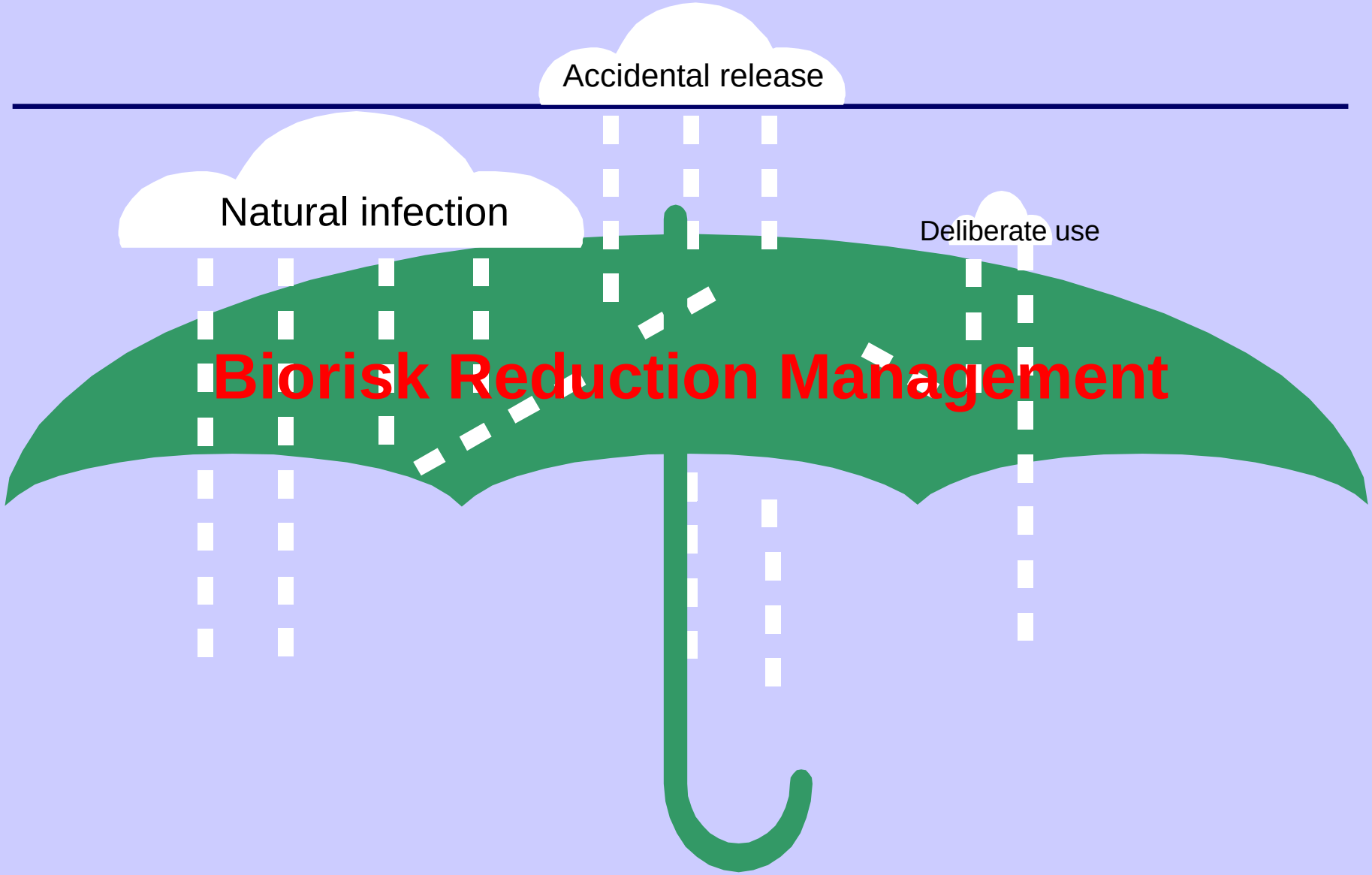


WHO 2007

In conclusion

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

Thank you

mohammadia@who.int