

NATIONAL EXPERIENCE IN BUILDING HEALTH SECURITY, RELATIONSHIP TO ARTICLE X IMPLEMENTATION



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I. Introduction

Introduction

- ❖ Indonesia signed the BWC in 1972
- ❖ Our country ratified the convention in 1991, under Presidential Decree 58/1991.
- ❖ The rationale behind the ratification of the convention is stipulated in paragraph IV to the Preamble of the 1945 Constitution of the Republic of Indonesia,

Introduction

- ❖ The BWC consists of 15 articles.
- ❖ These articles work collectively to eliminate the use of biological weapons and toxins for non-peaceful purposes
- ❖ Convention has made an important contribution towards the world community's collective efforts to eliminate the threat of weapons mass destruction. However, it seems that society remains vulnerable to biological weapon attacks.

Introduction

- ❖ The anthrax incidents in the United States in 2001 have shown us how vulnerable society is.
- ❖ For decades, the United Nations has played an important role in assisting the control of biological weapons, yet the threat of biological weapons still exists.
- ❖ Permanently protecting society from biological weapons remains difficult due to their ease of production and distribution

II. Article X of Biological Weapons Convention (BWC) and the Constraints of Implementation

Article X of the BWC

(1) The States Parties to this Convention undertake to facilitate, and have the right to participate in, the fullest possible exchange of equipment, materials, and scientific and technical information for the use of bacteriological (biological) agents and toxins for peaceful purposes.

Parties to the convention in a position to do so shall also cooperating in contributing individually or together with other States Parties or international organizations to the further development and scientific discoveries in the field of bacteriology (biology) for the prevention of disease, and for other peaceful purposes.

Article X of the BWC

- (2) The Convention shall be implemented in a manner designed to avoid hampering of the economic or technological development of States Parties to the Convention or international cooperation in the field of peaceful bacteriological (biological) activities, including the international exchange of bacteriological (biological) agents and toxins for peaceful purposes in accordance with the provisions of the Convention.

Importance of Article X

(according Gregory Stewart, US Department of State)

- ❑ All States Parties should cooperate and share information and agents to the degree possible without violation of other aspects of the Convention
- ❑ One infers that a state Party requesting assistance demonstrate that it is able to properly secure the agents provided to it.

It is very difficult to differentiate between peaceful and hostile purposes with respect to use of biological agents:

- ❖ First, most biological agents exist in nature. Many communicable diseases are endemic in certain region in our country.
- ❖ Second, we can't predict the motivation of the producer of the weapon, due to the simplicity of the methods to produce them and their materials and knowledge necessary to create and sustain a biological weapons program are widely available around the world.

3. A multi-interpretable approach, due to the vested-interest and their National regulation of each Member State

4. A lenient position of health as Ecosoc rights in compare with Civil & Political Rights, although Biological agents which have pandemic potential and misusing it as bioweapon close to Civil and Political Rights

**III. Indonesian Experiences in Implementing
Health Security Building Regarding
Article X of BWC by strengthening
National Laws and special policy**

RI's strong point on Biodiversity (as state party on CBD)

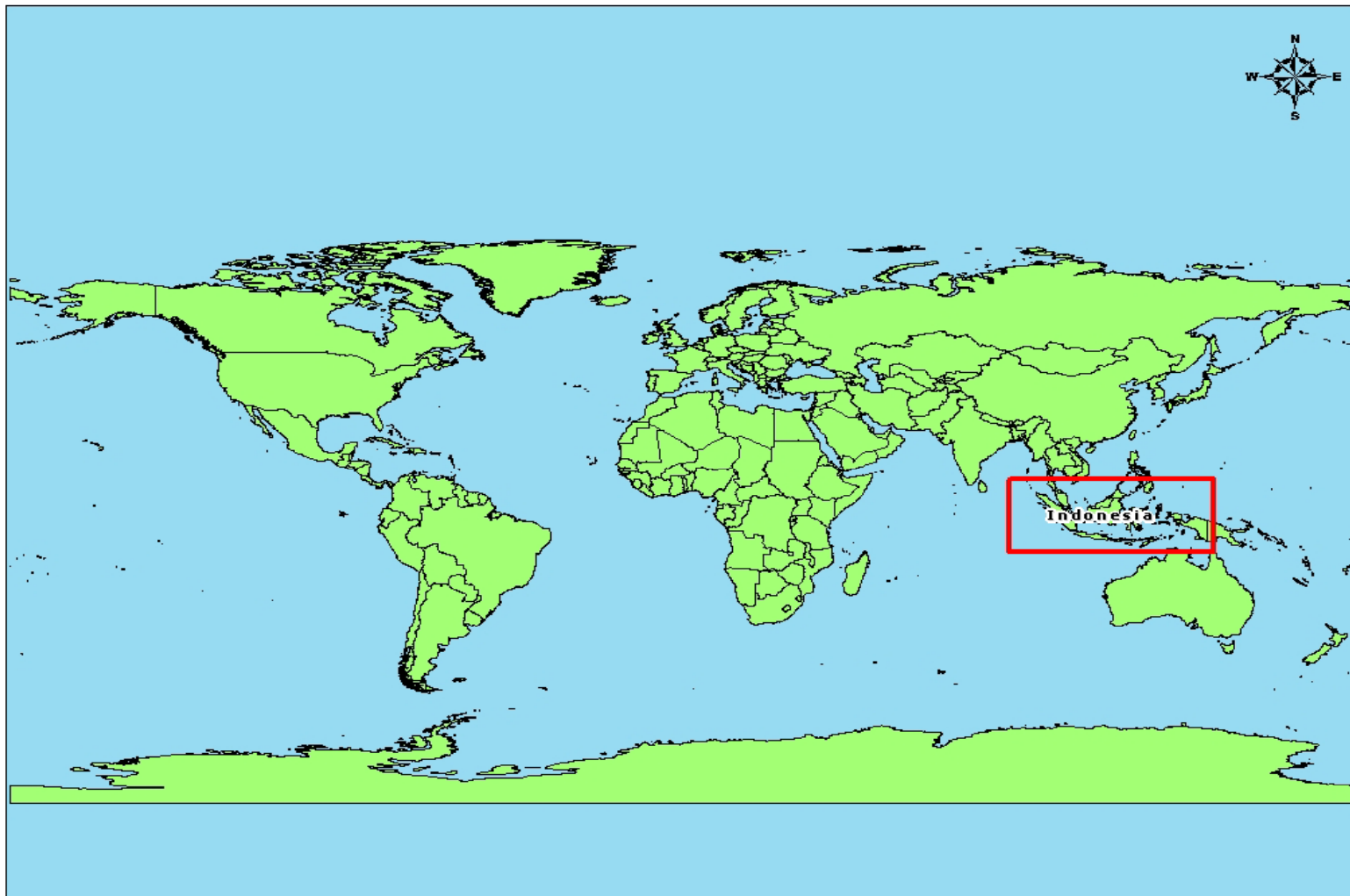
- Art 1 : RI's interest to the conservation and sustainable use of plant genetic resources for food and agriculture and the fair, transparent and equitable sharing of the benefits arising out of their use, in harmony with the CBD for sustainable agriculture and food security
- Art 3: RI's interest on conservation Biological Natural Resources and It's Ecosystem → aiming that biological natural resources preservation & balancing the ecosystem to suport improvement of health & community welfare and quality of human life.

Why must we pay attention to health security issue in Indonesia ?

Indonesia has some conditions that may pose as weaknesses for health security :

- Geographical condition as a huge country
- Some diseases patterns that are considered as “Biological Threat” (WHO) are endemic in certain areas of Indonesia i.e., anthrax and plaque
- Big proportion of population with low income capacity, poor health environment condition & health status
- Multi-ethnic conditions giving the possibility therein to become deviant groups (separatist or extremist groups) in certain parts of Indonesia

World Map



Geography, climate and population

- Indonesia consists of 5 major islands, +/-3,000 medium and 13,677 small islands
- The location is between two continents
- The total area is 5,193,250 km²
(39% land and 61% sea territory)
- It has dry and rainy seasons
- The range of temperature is from 20° C to 30°C and the humidity is from 65% to 90%

Map of Indonesia

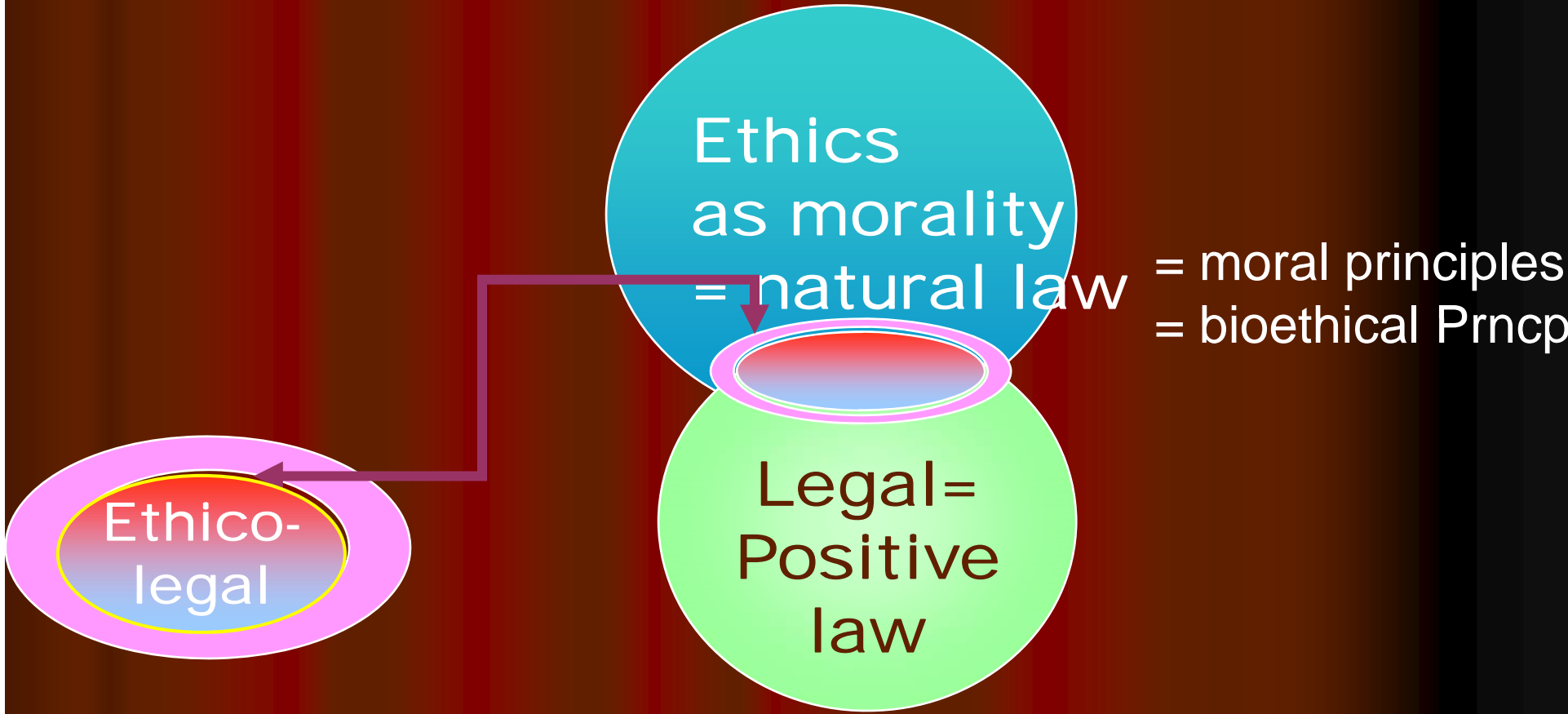


Geography, climate and population

- Indonesia is divided into 33 Provinces, 441 districts, 5.175 sub-districts and 66,721 villages
- Total population in 2003/2004 is 216,200,000 with pop. density of 113 persons per km²
- There are > 300 ethnic groups



Ethicolegal Perspectives



Law could be morally defect if >< Universal Declaration on Bioethics & Human Rights as universal norms

Ethicolegal approach

- Arise from an anomic condition → the “enlightened society” (including the health profession) have a deep concern to improve the people’s way of life to achive public’s common good
- Combine the value-based as a predecessor and evolving power of evidence-based health system
- Making a critical appraisal to the existing law and written health policy to be changed proportionately & reasonably

Some laws with biosecurity issues related to article X of BWC - as follows:

- ❖ *Act No. 5 of 1994 concerning the legalization of United Nations Convention on Biological Diversity*
- ❖ *Act No. 14 of 2001 concerning Patent*
- ❖ *Act No. 18 of 2002 concerning National System of Research, Development and Application of Science & Technology*
- ❖ **Act No. 4 of 2006 regarding Recognize of International Treaty on Plant genetic resources for food and agriculture**

Some Government Regulations regarding biosecurity related to article X of BWC as follows:

- ❖ *GR No. 27 of 2004 concerning Patent Procedural Mechanism by Government*
- ❖ *GR No. 20 of 2005 concerning Technology transfer of IP and the R&D Result of R&D Institutions*
- ❖ *GR No. 41 of 2006 concerning R&D licensure for Foreign Universities, R&D Institutions, corporations and foreigners*

Some MOH Decrees regarding biosecurity and article X of BWC as follows:

- ❖ No. 1244/MENKES/SK/XII/1994 regarding Guidelines on Biosafety in Microbiology and Biomedical Laboratories ⁹⁾, in progress of revision.
- ❖ No. 732/Menkes/SK/VII/2008 regarding Guidance of MTA
- ❖ *No. 1179A/SK/X/1999 regarding National Policy of Health R & D*
- ❖ No. 1333/SK/X/2002 regarding Research Licensure for Human research.
- ❖ No.1031/SK/VII/2005 regarding National Guidance for Health Research;
- ❖ No. 1423/E/XII/2006 to Director of Govt Hospital, Dean of School of Medicine regarding transfer prohibition of specimen abroad if NIHRD as Referral Laboratory for Communicable Diseases or any Domestic Research Institutes could able to conduct examination.

SPECIAL POLICY in accordance with IHR (2005)

- ❖ Establishing a MTA Review Team at NIHRD
- ❖ Develop SOP in Biosecurity in Infectious Disease Laboratory, especially BSL-3
- ❖ Submit Confidence Building Measures (CBMs) every year (via Min.of Foreign Affairs)
- ❖ Conduct risk assessment and improvement of biosafety and biosecurity in the Avian influenza regional laboratories
- ❖ Training of Biosafety and Biosecurity in the Avian influenza regional laboratories

SPECIAL POLICY

- Indonesia has become a state party to the biological weapons convention (BWC) as stipulated by Presidential Decree No. 58 of 1991, we will make special Act regarding The Use of BW → Assigning the MOH as focal point to draft → updating our national regulation
- The provisional content of the Act :
 - enacting criminal sanctions (criminalization) toward any individual/ group misusing or intentionally making any biological pathogens as BW
 - Authorizing government to regulate and supervise the use of materials for the purpose of Biology for peaceful purposes

The provisional content (2) of the Act :

- enacting embargo power of the state to any violation of importing the biological materials which can be use as BW
- The biosafety and biosecurity issues of any laboratory dealing with pathogens in line with Indonesian sociological and phylosophical standpoint.

RI's commitments :

Not to develop and having biological weapons (Art I BWC)

Will prevent misusing the pathogens by those who are unresponsible person or terrorist groups (Art. III BWC).

RI's contribution on building the WHO framework : Virus Sharing and Benefits Sharing

Agreement on Principles at the Resumed IGM-PIP 2008:

- Standard Material Transfer Agreement (sMTA) will be used when virus is shared,
- Virus sharing and benefits sharing stand at the same footing,
- Principles of benefits sharing are mentioned in the sMTA,
- Establishment of Advisory Mechanism
- Establishment of Tracking System

Biosafety (WHO)

The containment principle, technologies and practices that are implemented to prevent the unintentional exposure to pathogens and toxins, or their accidental release.

Biosecurity (WHO)

The protection, control and accountability for valuable biological material (VBM) laboratories, in order to prevent their unauthorized access, loss, theft, misuse, diversion or intentional release .

Basic Principles

- Clinical specimens, biological materials and non-biological materials of Indonesia belong to Indonesia and are protected by the Government
- Tests/managements of the above materials are to be conducted in-country
- Exceptions are allowed in certain conditions as stipulated in government regulations

❖ Laboratory biosafety and biosecurity i.e. our 4 BSL-3 in Jakarta & Surabaya, mitigate different risks, but they share a common goal : keeping valuable biological materials (VBM) safely and securely inside the areas where they are used and stored.

❖ Biosafety and biosecurity are complementary

Critical points

- International Research Collaboration
- Global & Regional Surveillance (eg., influenza like illness at 40 sentinel labs, SARI, polio) → at ASEAN + 3 MEETING : + 2 other criterion of pandemic : severity & lab genetic virology
- Supranational Laboratory for Quality Control and Quality Assurance (eg., TB, polio)
- International Training and Education
- Health Services
- Local-Foreign (International) Institutions (eg., Namru-2 Jakarta)

Protective Measures (1)

- MOU with International Collaborators and Local-Foreign International Institutions (for research, training, education)
- Followed by detailed Plan of Actions
- Advocacy to empower in-country laboratory capacities, internationally recognized

Protective Measures (2)

- Implementing MTA for all transfer/movement of clinical specimens, biological and non-biological materials from and to Indonesia
- Oversight mechanism by National Committees
- Develop tracking system through MTA Review Teams

Protective Measures (3)

(local)

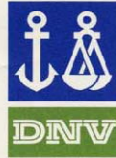
- Implementing measures of Biosecurity level 2 or 3 (depending on types of the works) in laboratories according to international standard
- Implementing SOP of high security in laboratories where viruses and bacteria are kept
- Implementing Laboratory Information Management System for recording, tracking and accessing specimens
- Maintaining a national laboratory network for infectious diseases

Handling and storage

- H5N1 and other dangerous viruses/organisms are kept according to the biosafety guides as recommended by WHO and other international agencies
- All procedures have met the protocols as determined for biosafety and biosecurity purposes and disarmament regulation
- All H5N1 viruses in Indonesia (returned from US CDC, Japan NIID and Hongkong, as well as from new cases) are kept in BSL lab at Eijkman Institute with international certifications for:
 1. the BSL facilities (building, instruments, mechanics, and all systems etc): DNV (Norwegian) certificate
 2. biosafety officer and staffs
 3. Standard operation procedures

Security aspects:

- Entrance to the BSL3 lab is limited to authorized personels only (with finger print identification)
- Doors and accesses to BSL3 are also limited (by finger print identification) and monitored by cctv cameras and digitally recorded
- Biosafety officers and staffs at Eijkman BSL3 have understood all regulation, and all data have been notified to the appropriate authority.



DET NORSKE VERITAS

CONTAINMENT LABORATORY CERTIFICATE

Certificate No. BSL3-2007-SEA-JAK-001

This is to certify that

The BSL3 Facility at the Eijkman Institute, Jakarta, Indonesia

Has been found to conform to the requirements of the WHO Laboratory Biosafety Manual (3RD Edition)

In relation to the building and associated equipment installed on site in terms of meeting the following principles*:

- Containment barrier integrity
- Suitable directional air flow
- Effective decontamination of
 - People / clothing
 - Equipment
 - Air
 - Waste (liquid, solid, cultures, etc.)
- Operational reliability and effectiveness during both normal working conditions and scheduled shutdowns; and in the event of a failure or emergency.
- Capability of being effectively maintained during planned and unplanned maintenance situations.

***(N. B. Certification at the date of issue excludes training plans / competency assessment, operational protocols and SOPs)**

Initial Certification date:
31st March, 2007

This Certificate is valid until:
31st March, 2008

Place and date:
3rd April, 2007

for:
DNV CERTIFICATION,
Singapore

The audit has been performed under the supervision of:

Dr Paul J Huntly
Lead Auditor

Mr Lim Jit Ting
Management Representative

Any significant modification or changes with potential to impact the containment principles stated above may render this Certificate invalid.

IV. Conclusions

Conclusion (1)

- ❖ Article X of the BWC, in terms of 'VALUE-FREE' of technological aspects based on BIOSAFETY approach, it has not been effectively implemented because of the difficulties (instead of not mentioning "impossibility") in differentiating or INTERPRETING between peaceful and hostile use of biological agents based on BIOSECURITY approach.
- ❖ The implementation of the ethico-legal aspect of the Convention becomes difficult too, because of the lack of any value verification on global advisory system that can be agreed on and the limitation of scientific tracking system of these agents

❖ Although there are some difficult aspects in implementing Article X of the BWC, Indonesia has a strong commitment to the Convention, by strengthening the national law and regulation inspired by the spirit of BWC using ethico-legal approach.

Thank You

