National Biosafety Framework in Nepal

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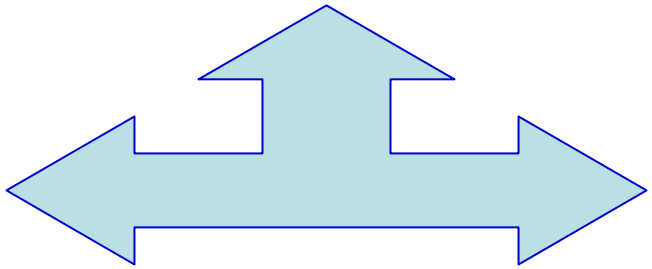
Country Background

- South of Himalayan Range
- Between China and India
- Area 1,47,181sq.km
- Elevation 60 m to 8848m-Mt. Everest
- Hills and high mountain-86%
- Terai plain-14% of total area of nation

Biological Diversity

Climatic Diversity

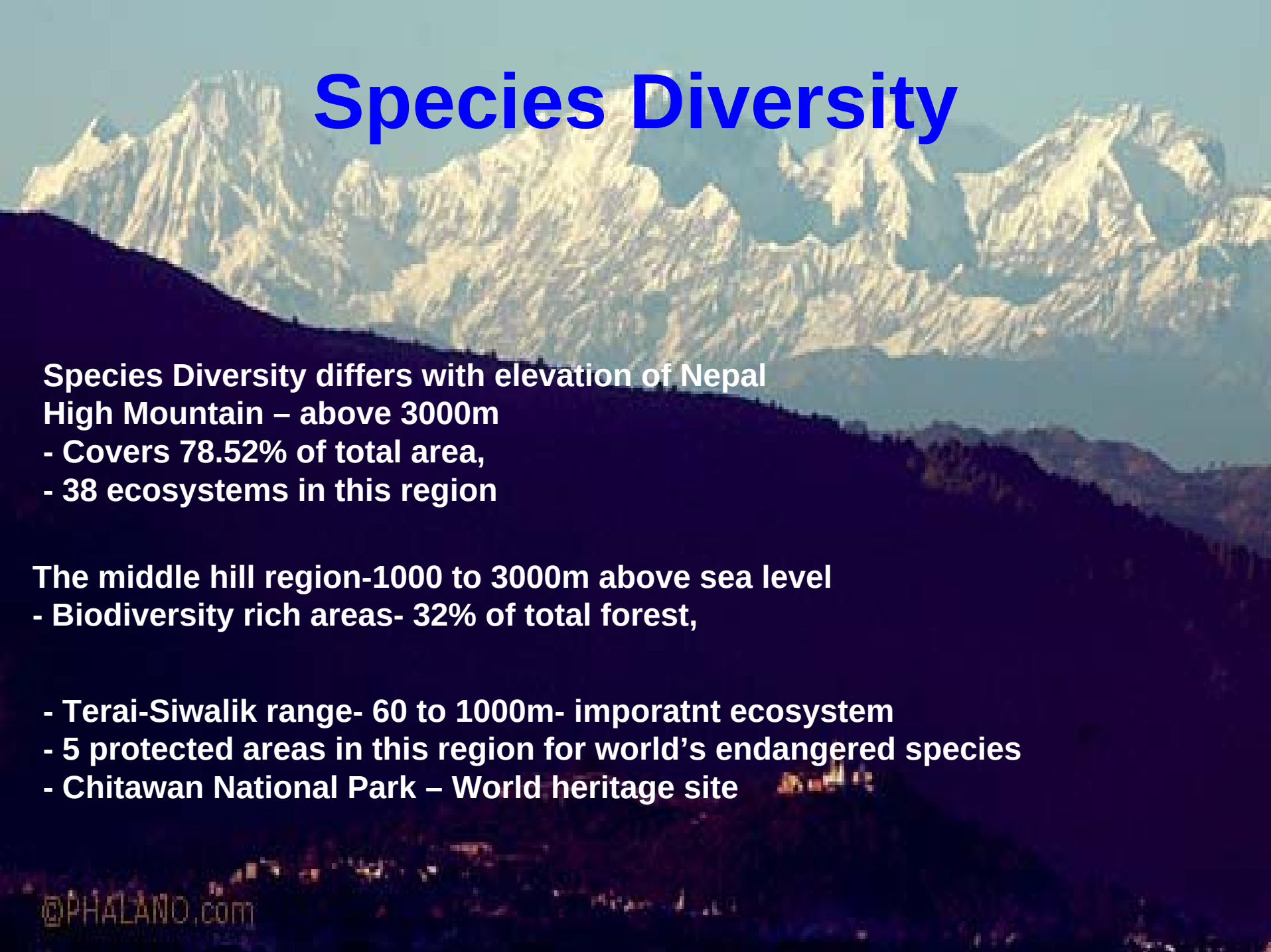


Peculiar Geographical Structure

- Climatic diversity- Diversity in habitat, plants and animals
- Seasonal variation-rains in monsoon, snowfall in winter, high temt. in summer
- One season- different climate in different landscape of nation

This is one of the reason for species diversity

Species Diversity



Species Diversity differs with elevation of Nepal
High Mountain – above 3000m
- Covers 78.52% of total area,
- 38 ecosystems in this region

The middle hill region-1000 to 3000m above sea level
- Biodiversity rich areas- 32% of total forest,

- Terai-Siwalik range- 60 to 1000m- imporatnt ecosystem
- 5 protected areas in this region for world's endangered species
- Chitawan National Park – World heritage site

1-Biodiversity:

- **Nepal Geographically small but rich in biodiversity**
- **Nepal represents-0.1% of terrestrial area of the earth but**
- **Has 118 ecosystem, higher presence of diff. flora and fauna**

- **15 sps. of vascular plants, 58 sps. of mammals, 40 sps. of birds,**
- **13 sps. of reptiles, 2 sps. of insects and 1 sps. of amphibian belons to CITES list.**

- **342 plant sps & 160 animal sps. are Endemic to Nepal**

- **Biodiversity closely links to –**
- **Nepalese livelihoods, economic development, agricultural system, human health and protein, construction material, water resource & society's cultural values.**
- ***Source: Nepal Biodiversity Strategy (NBS), 2002***

Nepal's richness in Organism as Compared to the World

Gr. Of Organism	Nepal's representation as compared to the no. of species in the world
Lichens	**2.3**
Fungi	**2.4**
Algae	**2.6**
Bryophytes	**5.1**
Pteridophytes	**3.4**
Gymnosperm	**5.1**
Angiosperm	**2.7**
Spider	**0.2**
Other insects	**0.7**
Butterflies & Moths	**2.6**
Birds (>850sps)	**9.3**
Reptiles	**1.6**
Amphibians	**1.0**
Fishes	**1.0**
Mammals	**4.5**
Sources:NBS, 2002	

Nepal's biosafety policy is based on precautionary principle:

- **And based on conservation of rich biodiversity**
- **Protective measures for indigenous agricultural system**
- **Srict regulation on GMO, LMO & Hybrid & its transboundary movement**
- **But less attention on pathogen, micro-organism & possible bioterrorism**
- **Development & application of Biotechnology where comparative benefits can be achieved.**

Nepal's international obligation

- Commitment to Biosafety by Signing the Cartagena Protocol- 2nd March 2002
- To pay attention to transboundary movement of GMOs, on the basis of advanced informed agreement.
- Laws and policies related to the release, use and marketing of GMOs have to be formulated as per the provision of the Cartagena Protocol.

2:Policy Aspects of Biosafety in Nepal

1- Sustenable Development Agenda 2003

2- Millenium Development Goals (MDGs) 2000

3- The Tenth Plan (2002 – 2007)-stress on biotech, bioeng. & biosafety.

4- Nepal Biodiversity Strategy, 2002

5- Nepal Biodiversity Strategy Implementation Plan(NBSIP)-2006-07

6- National Wetland Policy, 2002

7- Science & Technology Policy, 2002

8- **Biotechnology Policy, 2006**

9- Biosafety Guidelines, 2005 by Minst. Of Forest & soil Conservation

10- Agricultural Policy, 2005

11- National Seed Policy, 1997

12-National Biosafety Policy, March 1, 2007

Legal provisions relating to biosafety

Although not specific, many legal provisions are found to have in place long before the emergence of the concept of biosafety itself.

1- Local self governance act 1999.
2- Consumer protection act, 1997
3- The export import act, 1956
4- Plant protection act, 1972
5- Seed act, 1989
6- Food act, 1966
7- Feed act, 1966
8- Animal health & livestock service act, 1998
9- Slaugheter house and meat inspection act, 1999
10- National dairy development board act. 1991
11- Nepal agricultural research council act, 1991
12- Drug act, 1978
13- National park and conservation act, 1972
14- Forest act, 1999
15- Aquatic animal protection act 1960
16- Environmental protection act, 1997
17- The patent, design and trademark act, 1965

The Proposed Legal Frame Work for Biosafety

- Function is to make biosafety bill with the following provisions:

1- Objectives

2- Scope

3- Definitions

4- Institutional set up (MFSC as national focal point & NBC-national biosafety committee) representation from different sectors

5- Proposal Submission with Risk assessment & Management Report

6- Environmental Impact Assessment (EIA)

7- Public hearing

8- Decision on proposal

9- Determination of biosafety standard

10- Packaging and labelling

11-Monitoring, inspection and emergency response

12- protection of confidential information

13- Declaration of GMOs Free Zone

14- Provision of biosafety officer, 15- Offences & penalties,

16- Biosafety fund, 17- Capacity building

3-Technical Aspects of Biosafety

3.1-Technical frame work covers

A- The scientific research

B- Testing of seed, plants, food, feed and animals with GMOs which may be imported or produced within the country

C- identification, characterization and analysis of the components of GMOs

D- Decision making for import and export.

E- management of risk

3.2- Potential Risk as mentioned in the policy

A- Potential risks of plants GMOs and their product

I- Expression of toxic or allergenic compound

II- Effects on biogeochemistry

III- Transfer of disease resistant, insect pest resistant, herbicide resistant genes to wild species, cultivated or domesticated wild or semi wild sps.

IV- Transfer of genetic material(bacterial, fungal, viral) i.e. gene flow via pollination to wild, cultivated or domsticated.

V- Instabilty of genetic modification

VI- Unintended genetic modification to adverse effects

VII- Issues of impacts of new traits on target & non target organism

B-Potential risk of genetically modified Micro-organisms

I- Diseases of human & animal, toxic or allergenic effects

II- Epidemic in agricultural and natural environment

III- Adverse effect from instabilty to treat diseasea

IV- Adverse effects to ecolgical & biogeochemical cycle resulting from GMOs introduction

V- Adverse effects resulting from natural transfer of inserted genetic materials to other organism

C-Potential risk of genetically modified animals & product

I- Adventitious infectious agent transfer

II- Endogenous retroviral activation

III- Entopic expression of transgene (in non target tissues)

IV- Excess production of transgene or metabolites

V- Pleiotropic effects of transgene expression (unpredicted effects on the expression of other genes

VI- Prion disease susceptibility hazards

VII- Leakage of expressed products from target tissues

3.3 Need of Technical Framework

Technical management for risk identification:

A- Prior to permitting release of GMO, the GMO in question should subject to an adequate period of observation, at least to its life cycle or generational time.

B- GMOs package & products need to have labelling with general information on GMOs and potential allergenic

C- Application of accepted risk management by different countries & its risk level:

I- physical- (separation of areas for GMO test)

II- chemical- (sterilization of the used instruments & media)

III- biological- (establishment of biological buffer areas)

D- To ban certain products (marked with antibiotic resistance)

E- To prohibit certain activities or work for risk avoidance

F- Application of emergency measures

3.4 Existing situation:

Technology, Human resources and Infra structure

A- Biotech. lab, Tissues culture lab, Parasitological & Microbiology lab with PCR machine

B- Human resources available in Plant and Animal Mol. Biology, Tissue culture, microbial Mol. Ecology, Forensic.

C- Engaged in research & development activities

D- Plant Biotech:- Tissues culture- Potato, Banana, Citrus and Flowers

E- Disease diagnosis, genetic diversity study, biofertilizer, microbial bio-pesticides, livestock vaccine (anti rabies), embryo transfer in livestock,

F- Private sectors:- involved in Tissue culture technology in agriculture & horticulture.

G- Government sectors: NARC, NAST, CVL, Nepal Forensic Lab(for DNA fingerprinting)

H- Available technical human resources are not enough for National Biosafety Program

3.5 Proposed Technical Framework

A- Biosafety lab: Existing microbiology lab will be developed as reference lab checking & verifying proponents's information on GMO.

B- Risk examination & management by SECTORAL COMPETENT AUTHORITY

C- Capacity building-

I- of institution for biosafety related R & D.

II- of central to district level institution for Risk assessment & management.

III- in GMO detection techniques

IV- rDNA safety guidelines

V- Improving Quarantine offices

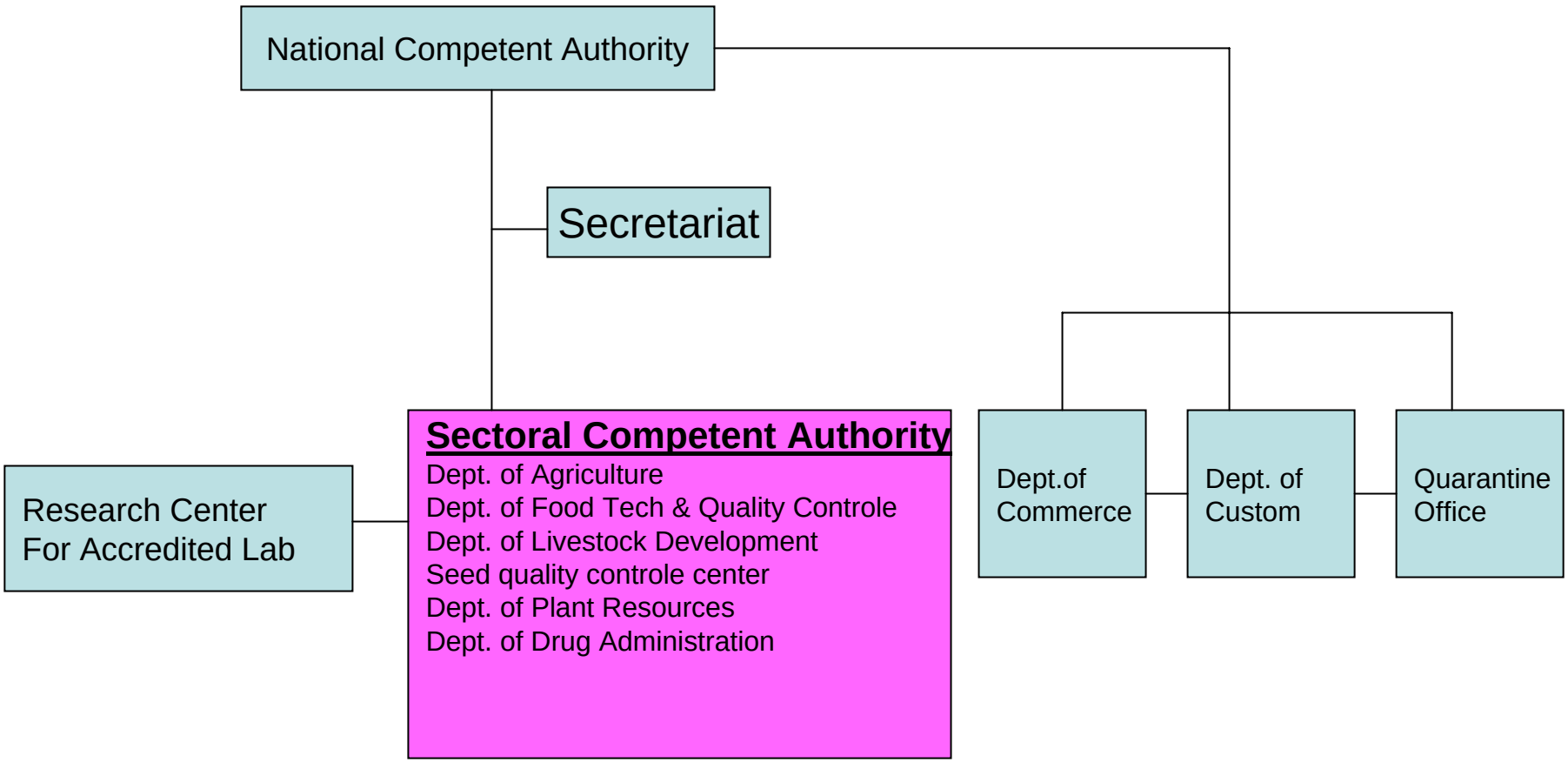
VI- Development of technical guidelines for GMO & products

VII- in labelling GMOs

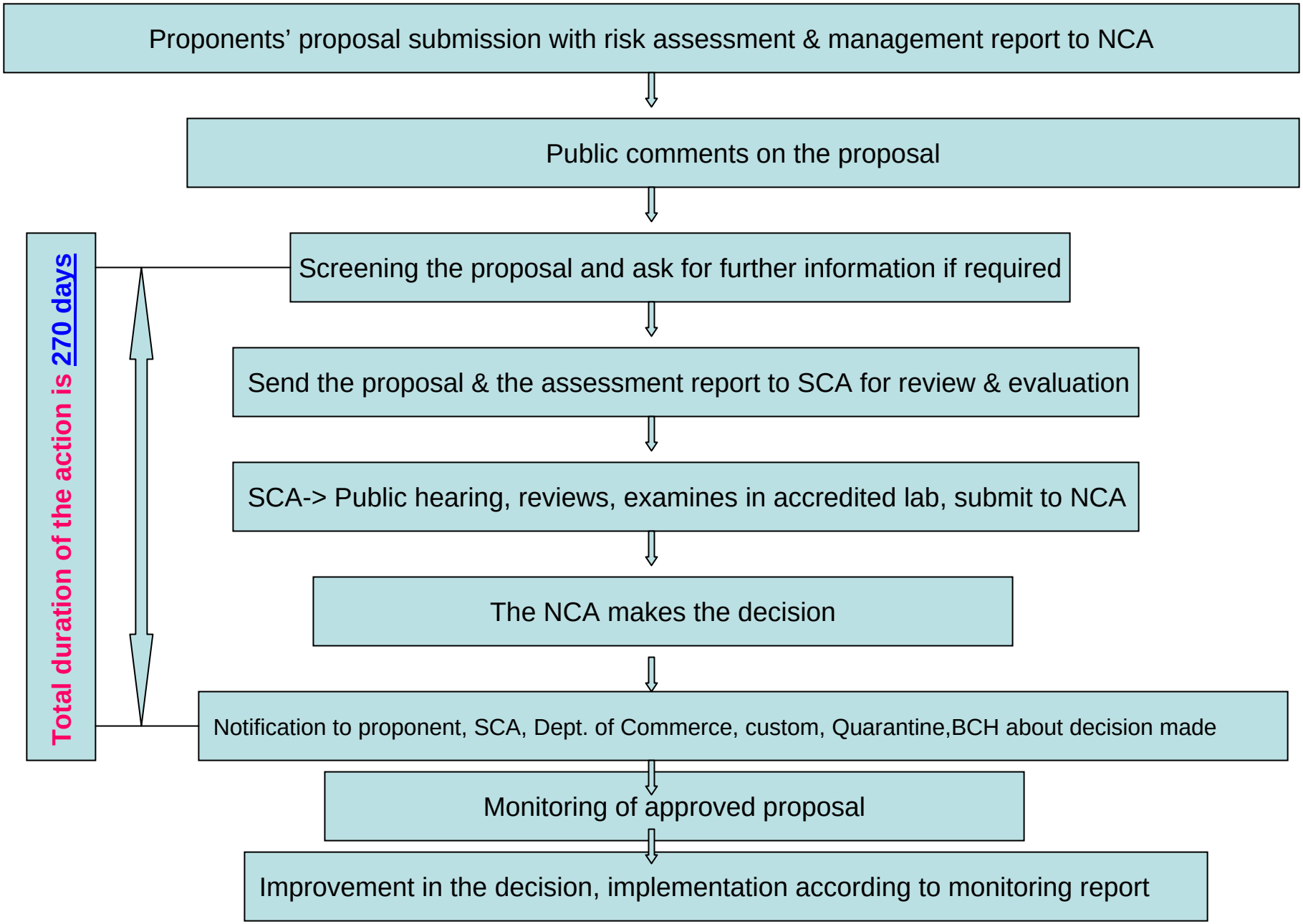
VIII-Develop Biosafety Technology

4: Administrative Aspects for Biosafety

Decision making and implementation mechanism



Inter-linkage among the institutions involved in the decision making process in biosafety



Flow chart of a decision making and implementation of a proposal on GMOs or its products

Gaps in Nepal's National Biosafety Frame Work and Lesson from Developed Countries for Dual Use & Pathogen & Micro-organisms

International Collaboration

1.Global Health Alert Network
Global Biosecurity Action Group Net

2.Global Biosecurity Laboratory Net

3.WHO, US CDC, Pasteur Institute, China & Korea CDC, Taiwan CDC and other foreign National Health Institutes

Cooperation with international organization to be done now

- American Biological Safety Association (ABSA)
- European Biological Safety Association (EBSA)
- Asia-Pacific Biological Safety Association (A-PBS)
- WHO;HQ/WHO;WPRO ;CISSM
- Others

Biosecurity Strategy on Pathogens

Law concerning anti-bioterrorism

- **USA** 2003 active
  Possession, Use, and Transfer of select Agents and Toxins

- **UK** 2001 active
  Anti-terrorism, Crime and Security Act2001
  Part7 Security of Pathogens and Toxins

Regulation on Biosafety

- Directive 2000/54/EC of The European Parliament and of the Council of 18 September 2000 on the protection of workers from risks related exposure to biological agents at work
  Each country has made domestic law based on the Directive

- **China** 2004
  Prevention and therapeutic law on communicable diseases, China.

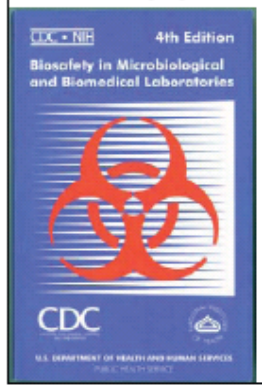
International Standard on Handling Pathogens

Biosafety

- **WHO**

Laboratory Biosafety Manual 3rd Edition

- **米国CDC**



Biosafety in Microbiological and Biomedical Laboratories (BMBL) 4th Edition
5th Edit on web

Biosecurity

- **WHO** ***Laboratory biosecurity (Laboratory Biosafety Manual Part II)***
  9.Labortory biosecurity concepts
  Laboratory biosecurity guidance **(** Biorisk management **)**

- **USA CDC** ***Laboratory Security and Emergency Response Guidance for Laboratories Working with Select Agents***

Regulation on the Safety Control of Laboratories Handling Pathogenic Agents, A lesson from NIID, Japan and other Developing Nations,

1.Risk Classification of microbiological agents

2.Relation of risk groups to biosafety levels, practices and equipment

3.Facility requirements at the four biosafety levels

Safety Organization and Training

Biosafety Office (permanent and temporary staffs):
Responsible for all issues on biosafety and biosecurity

Training Course : bimonthly,

Reporting System:

Material Transfer Agreement,

Permission and reporting of pathogen for handling, transfer, acceptance, etc.

Reporting on accident in the laboratory.

Other issues

4.Biosafety Guidelines

1). Risk assessment

2). Basic laboratory BSL-1, 2

3). Containment laboratory BSL-3

4). The maximum containment laboratory BSL-4

*All laboratories should have the own operation manual

5). Laboratory animal facilities ABSL-1 to 4

6). Guidelines for laboratory certification

- *Source: Takeshi KURATA , 2007,*
- *Regional Biosecurity workshop, Singapore*

Discrepancy of Classification of the Pathogens

NIID	LCPIMCPI	CDC	WHO*
Level 1	Group 1	BSL-1	Risk G 1
Level 2	Group 2	2	Risk G 2
Level 3	Group 3	3	Risk G 3
Level 4	Group 4	4	Risk G 4




Source: Takeshi KURATA , 2007, Regional Biosecurity workshop, Singapore

* WHO doesn't specify the agent

National (Regional) Classification of Micro-organisms by Risk Group

1. Pathogenicity of the Organisms

2. Mode of transmission and host range of the organism.
   These may be influenced by existing levels of immunity in the local population, density, presence of appropriate vectors and standards of environmental hygiene.

3. Local availability of effective preventive measures. Prophylaxis by immunization or administration of antisera, sanitary erasure, food, water hygiene, control of animal reservoirs.

4. Local availability of effective treatment. passive immunization, postexposure vaccines and use of antimicrobials, antivirals and chemo therapeutic agents,
   possibility of the emergence of drug-resistant strain.

Source: Takeshi KURATA , 2007,
Regional Biosecurity workshop, Singapore

Select Agents are classified into 4 Groups

I Usually forbidden to possess, use, import, etc. except for diagnosis and research necessary for public health.

II Need permission of the Minister of Health, Labourand Welfare to possess, use, import etc.

III Report to the Minister for possession, use, import, etc.

IV Follow the rule for storage, use, disposal, etc

Source: Takeshi KURATA , 2007,

Regional Biosecurity workshop, Singapore

Group 1（6）

Forbidden: Possession, use, import, transfer etc

- Ebola virus
- Crimean Congo virus
- Variolavirus
- Marburg virus
- Lassa virusSouth
- America hemorrhagic fever virus

（ Guanarito, Junin, Machupo,Sabia ）

Group 2 (6)

Need permission for possession and import and control of transfer

- Plague
- SARS Corona virus
- Anthrax
- Tularemia
- Botulinus
- Botulinus toxin

Group 3 (21)

Need report of possession, import, transfer

- Q fever Coxiella
- Rabies virus
- MDR MTb
- Coccidioides immitis
- Monkey pox
- HFRS
- Nipha virus
- Brucellosis
- B virus
- Burkholderia mallei, pseudomallei
- Venezuelan, Eastern and Western Equine Encephalitis
- Rocky Mountain spotted fever, Typhoid fever, Spotted fever japonica rickettsia
- Tick-borne Encephalitis and hemorrhagic fever virus
- Hendra virus
- Rift valley fever virus
- HPS virus

Group 4 (16)

Follow the handling rule

Westnile fever virus

H2N2 influenza virus

Yellow fever virus

Chlamydia psittaci

Cryptosporidium

Cholera

Mico. tuberculosis, excluding MDR-MTb

Polio virus

Shigella

Typhus-Palatyphus

Enterohemorrhagic E coli.

Dengue virus

Avian influenza virus

Japanese encephalitis virus

Shiga toxin

What We Need Now ?

- Emerging & Re-Emerging Infectious Diseases
- Biodefence

Strengthen the Active Surveillance

Promotion of Basic Research of Pathogens Including Genetic Analysis

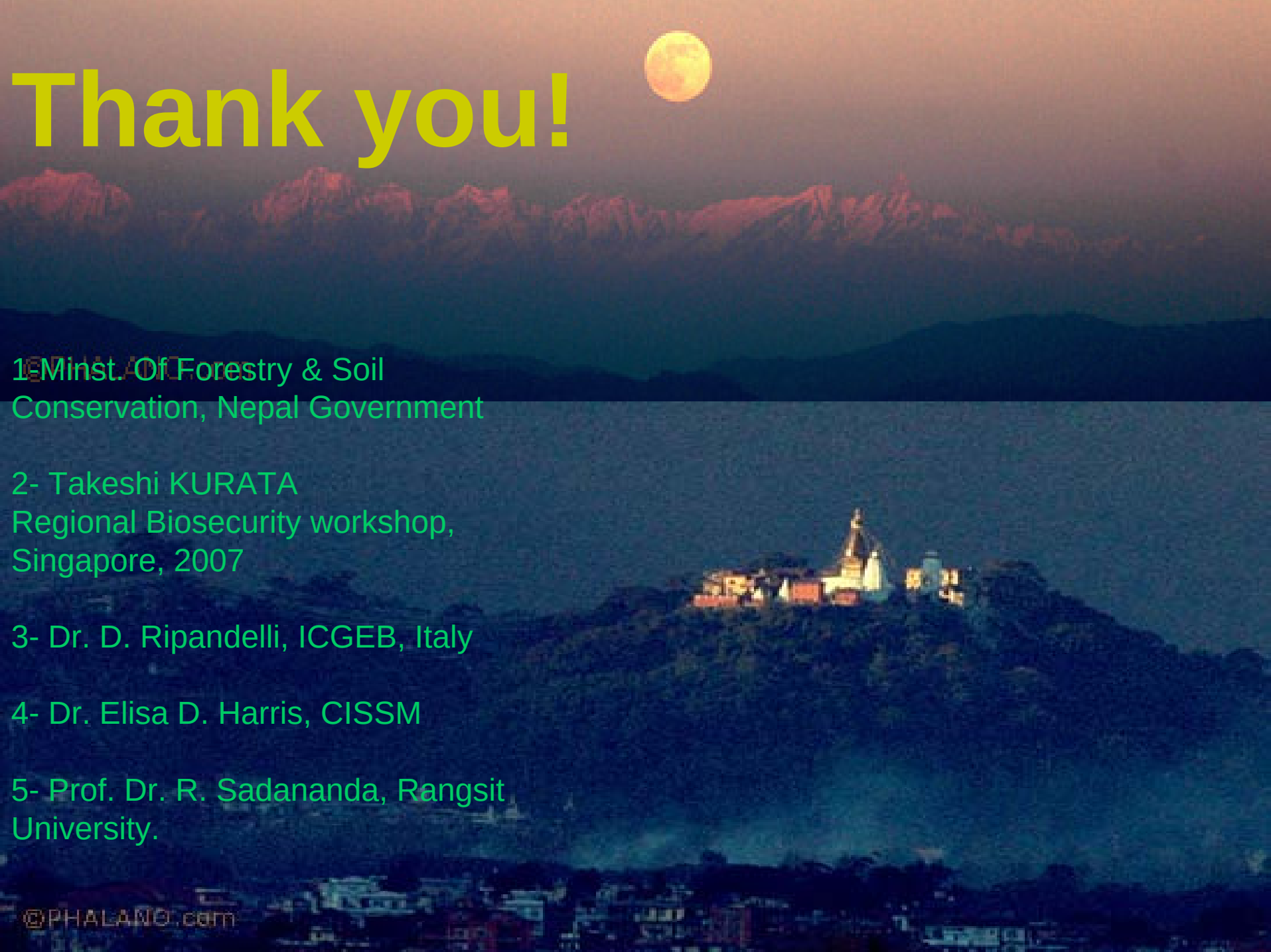
Technical Development

① Vaccine for Prevention
② Diagnosis Technology
③ Drug / Therapy

Enhancement of the Basis of Infrastructure Preparation (Facility, Devices, Personnel, Training, Information Network – Domestic & International)

Source: Takeshi KURATA , 2007, Regional Biosecurity workshop, Singapore

Thank you!



1-Minst. Of Forestry & Soil Conservation, Nepal Government

2- Takeshi KURATA
Regional Biosecurity workshop, Singapore, 2007

3- Dr. D. Ripandelli, ICGEB, Italy

4- Dr. Elisa D. Harris, CISSM

5- Prof. Dr. R. Sadananda, Rangsit University.