



# **Strengthening Oversight on dual use Biotech Research in Asia (The Philippine Perspectives)**

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**CISSM Regional Biosecurity Workshop**

**Singapore May 28-30, 2007**

# Issues on Dual use Biotech Research

- 1. Challenges associated with implementing new oversight requirements in the Philippines**
- 2. Legal and cultural differences that need to be addressed**
- 3. Perception of threat in the Philippines**
- 4. Types of incentives that might facilitate participation by scientists**

# Issues on Dual use Biotech Research

1. & 2. Challenges associated with implementing new oversight requirements in the Philippines ; Legal and cultural differences that need to be addressed
- ➔ Incorporating dual use Biotech research regulations into existing ones

# NATIONAL GUIDELINES FOR BIOMEDICAL and BEHAVIORAL RESEARCH (DOST- PCHRD)

- National Guidelines for Biomedical Research
  - General
  - Rights of human participants
  - Clinical trials
  - HIV/AIDS research
  - Organ transplantation research
  - **Genetic engineering research**
  - Assisted reproductive technology research



# Biosafety Regulations in the Philippines

- Genesis relevant to use of modern biotechnology in the country (1987)- scientists' initiative to regulate the importation, movement and use of GMOs in the Philippines
- National Committee on Biosafety of the Philippines (NCBP) – established in 1990 → first BIOTECH regulatory system in ASEAN Region
- Institutional Biosafety Committee and Technical Review Panel: essential roles in regulatory process → draft guidelines to ensure that experiments using GMOs do not pose unacceptable risks to human health and the environment

# National Committee on Biosafety of the Philippines (NCBP)

- 4 National line agencies represented in NCBP: Departments of Agriculture, Science and Technology, Health and Environmental Resources
- 10 Members: USec of R & D of DOST as chairman, representatives from DOH, DA, DENR, biological scientist, environmental scientist, physical scientist and social scientist and 2 community representatives

# NCBP Functions per EO 430

- Identify and evaluate potential hazards involved in genetic engineering experiments and recommend measures to minimize the risks
  - Formulate and review national policies and guidelines on biosafety and on risk assessment of work in biotechnology
  - Develop working arrangements with government quarantine services and institutions in evaluation, monitoring and review of projects
  - Assist in developing technical expertise , facilities and other resources for quarantine services and risk assessments
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- ➔ Legal mandate of NCBP includes GMOs as well as potentially harmful exotic species
  - ➔ NCBP not a full time committee
  - ➔ Authority covers only experimental use of GMOs , not commercial use

# NCBP Biosafety Guidelines

- First Guideline issued in 1991
  - ➔ covers primarily the importation, transport and contained use of GMOs; contains procedures for evaluation and required containment levels for each activity
  - ➔ Criteria for evaluation: transformation protocol, genetic and physiologic analysis of donor organisms and GMO, assurance that no viable genetic material escapes and disposal of used materials resulting from the experiment



# NCBP Biosafety Guidelines

- Second Guideline issued in 1998
  - ➔ Covers the release of GMOs and Potentially Harmful Exotic Species into the environment
  - ➔ established the criteria for field testing of GMOs
  
- Unique feature of the guidelines is the provision for a public notice and comment period before the NCBP takes final action on any field test proposal

# Department of Agriculture AO # 8 (Series 2002)

- Regulates the commercial use of GMOs
  - ➔ regulates the importation and release into the environment of plants and plant products derived from the use of modern biotechnology
  - ➔ The approval of DA AO # 8 took almost two years: drafting the provisions and holding consultations among various stakeholders: scientists, regulators, farmers, food manufacturers, consumers, academe, government and Non-governmental organizations

# Issues on Dual use Biotech Research

## 3. Perception of Bio-terrorism threat in the Philippines

- The worldwide nuclear, biological and chemical warfare threat is under discussion in various government agencies like the National Security Council (Dir. Lorenzo Clavejo, Nov 2006 presentation for the DOH-HEMS consultative meeting on health emergency management)
- Countries with bioterrorism capabilities reviewed, especially those within the Asean region
- Biological warfare agents identified anthrax, plague, smallpox, ricin and botulinum toxin
- Well coordinated planning, detection, emergency response, communication programs and systems are currently being formulated at the national level

# Philippine Preparedness Plans

## NSC coordination:

- Preparation of educational materials to inform and assure the public before, during and after a biological attack
- Appropriate advisory and bulletins to our people on NBC attacks
- Enhancement of bioterrorism related education and training to key sectors
- Study possibility of stockpiling vaccines and drugs
- Encourage citizens' participation in ensuring intelligence gathering against terrorists in each barangay

# Philippine Preparedness Plans

Department of Health- Health Emergency  
Management Staff under Director  
Carmencita Banatin

Talking points on strengthening existing  
counter-terrorism cooperation in the  
subregion (Inputs for Meeting in Jakarta)

➔ Provides sectoral-wide coordination and  
development on health emergency  
preparedness and response : 11 national  
government and NG agencies

# Philippine Preparedness Plans

11 national government departments and NG agencies :

- National Defense
- Interior and Local Government
- Social welfare & development
- Transportation and Communication
- Education, Justice, University of the Philippines Manila, Phil Medical Association, Phil Hospital Association, Phil National Red Cross and Phil Society of Sanitary Engineers

# **Protocols/ Guidelines for management of Mass Casualty Incidents (MCI)**

- 1. National Policy on Health Emergency Management**
- 2. Implementing Guidelines for managing MCIs during emergencies and disasters**
- 3. Health Emergency Alert Reporting system**
- 4. Adoption and implementation of Code Alert System for DOH hospitals during emergencies and disasters**
- 5. Designation of HEM Coordinators**
- 6. Manual for Operation Centers in the DOH Central Office**

## **Protocols/ Guidelines for management of Mass Casualty Incidents (MCI)**

7. Hospital Networking system in Metro Manila
8. National Laboratory Biosafety and Biosecurity Action Plan
9. Template for a hospital emergency preparedness and response plan
10. Draft guidelines to assess national capacity to manage health risks of deliberate use of biological and chemical agents
11. Pocket emergency tool



# Issues on Dual use Biotech Research

4. Types of incentives that might facilitate participation by scientists

→ Philippine scientists try to be pro-active in many issues

→ Those in government service are more readily involved in training and assessments workshops → support for such trainings are always welcome

# Summary statements

- We have established the biosafety regulations for the importation and transport of genetically modified organisms for R & D and for commercialization
- These need to be reviewed to include more specific guidelines for oversight on dual use Biotech Research
- Strengthening oversight on dual use Biotech Research in the Philippines could be justified in line with perceived biological warfare threats , together with nuclear and chemical threats in the region.

