

# Biosafety and Dual-Use Scientific Research.

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# Dual-Use

- Already precisely defined?
- Where are the limits?

# Risk and Perception.

- Risk increases with:
  - development in biotechnology.
  - lack or insufficient control.
  
- Risk perception influenced by:
  - education/culture.
  - specific knowledge about Biosafety.
  - media.

There are differences between developed and underdeveloped countries.



Different positions regarding this item.

# Biosafety in Cuba.



# Biosafety in Cuba.

## Particular issues.

- All research facilities belong to government.
- Biosecurity is included in Biosafety.
- Biological agents comprises those related with human, animal and plant health.
- Deals with traditional and GMO's organisms.
- Protects laboratory workers, community & environment.



# Definición de Bioseguridad. CUBA.

- Conjunto de medidas científico-organizativas y técnico-ingenieras.
- Destinadas a proteger: trabajador de la instalación, la comunidad y el ambiente.
- De: los riesgos que entraña el trabajo con agentes biológicos o la liberación de organismos al ambiente (OGM o exóticos).
- Para: prevenir daños y disminuir efectos y eliminar consecuencias en caso de contaminación, efectos adversos, escapes o pérdidas.

# Background.

Isolated scientific leaders.



Concern about occupational  
biological hazards.



Safety empirical measures to protect their  
own laboratory workers.

[Not complete or organized actions].



# Middle 60's and during 70's

- Hospitals increased in number and variety of services.
- Public Health Laboratory Network grew.
- New research centers were created.
- Set up a growing biotechnological and pharmaceutical industry.

# In the 80's.

- The Scientific Pole of Western Havana was founded.
- Biosafety Commission of the Cuban Academy of Sciences (ACC) was establish.
- Assessment the design of new facilities or remodeling existing ones.

# Between 1991 and 1996.

- Specialist working in this field increase in number and diversity, creating truly interdisciplinary groups.
- Nexus with activities of the Biological and Toxin Weapons Convention (BTWC).  
Annual reports and Conferences.
- Biosafety courses were done on annual basis.

# In the last decade.

- Approval of national laws and regulations.
- Growing relationships with other organizations.
- Biosafety start putting attention to issues related to biodiversity, quality control, medical care and others activities related to the economic and social life in the country.

In 1996 was created the National Center for Biological Safety (CNSB).

Main structure:

- Department of Inspection and activities related to BTWC.
- Department of Safety Analysis (Risk Assessment).
- Department of Teaching and Development.

# Subordination.

Ministry of Science, Technology and Environment (CITMA).



Office of Environmental Regulation and Nuclear Security (ORASEN).



CEANPAQ

CICA

CNSN

CNSB



# National Relationships of CNSB.

CNSB



Specialists

Territorial Deleg.

CITMA (14 Prov.

+ Special Mun.)

Metod. Adv.



Metod. Adv.



OACE

(Ministries)



Provincial  
Adm.

# International Relationships of CNSB.

- Secretaria del Convenio de Diversidad Biológica.
- Departamento de Desarme de Naciones Unidas.
- Proyecto del Fondo Mundial para el Medio Ambiente (PNUMA).

# Laws & Regulations

- Background:
  1. Ley 13/77 de Prot. e Higiene del Trabajo.
  
- Basic legal documents:
  1. Res. 67/96 CITMA: Creation of the CNSB.
  2. Ley 81/97: Environmental Law.
  
- Specific legal documents:
  1. Decreto-Ley 190/99 About Biological Safety.  
\*It is the top specific document.

# Complimentary Regulations (1).

1. Res. 42/99. Res.38/06 (update): List of biological agents.
2. Res. 8/00: General Regulations of BS.
3. Res. 76/00: Autorizations (licenses).
4. Res 103/02: Requirements and Procedures in Fac.

# Complimentary Regulations (2).

5. Acuerdo 4728/03: Appoint the National Authority for the BTWC.
6. Res. 112/03: BS Requirements for working with Plants and Animals.
7. Res. 2/04: Accountability and Control.

# Others.

- Decreto-Ley 200: De las Contravenciones en Materia de Medio Ambiente.
- Technical Committee for Standards No. 94 / Biological Safety. National Office for Standardisation.



# Some Interesting Activities.

- Visits of the Center for Defense Information (USA) to research center in Cuba.
- IAP. Codes of Conduct for Biological Scientists. Cuban Academy Workshop: Scientist Point of View. 2005.
- WHA.58.29 Enhancement of Laboratory Biosafety. PAHO efforts/ Regional meetings SP 2005; Guatemala 2006.
- IHR 2005.

# Some Challenges.

- Developing a “culture” of Biosafety.
- What to control and how without limiting development.
- Harmonization (in spite of many differences).
- To consider also animals and plants.

**Biosafety (and Biosecurity)  
is not an option. It is a  
crucial need for the  
development of biological  
sciences that can not be  
postponed.**

***Thanks!***