

# Latin America Laboratory Biosafety and Biosecurity Conference

Rio de Janeiro, May 2008

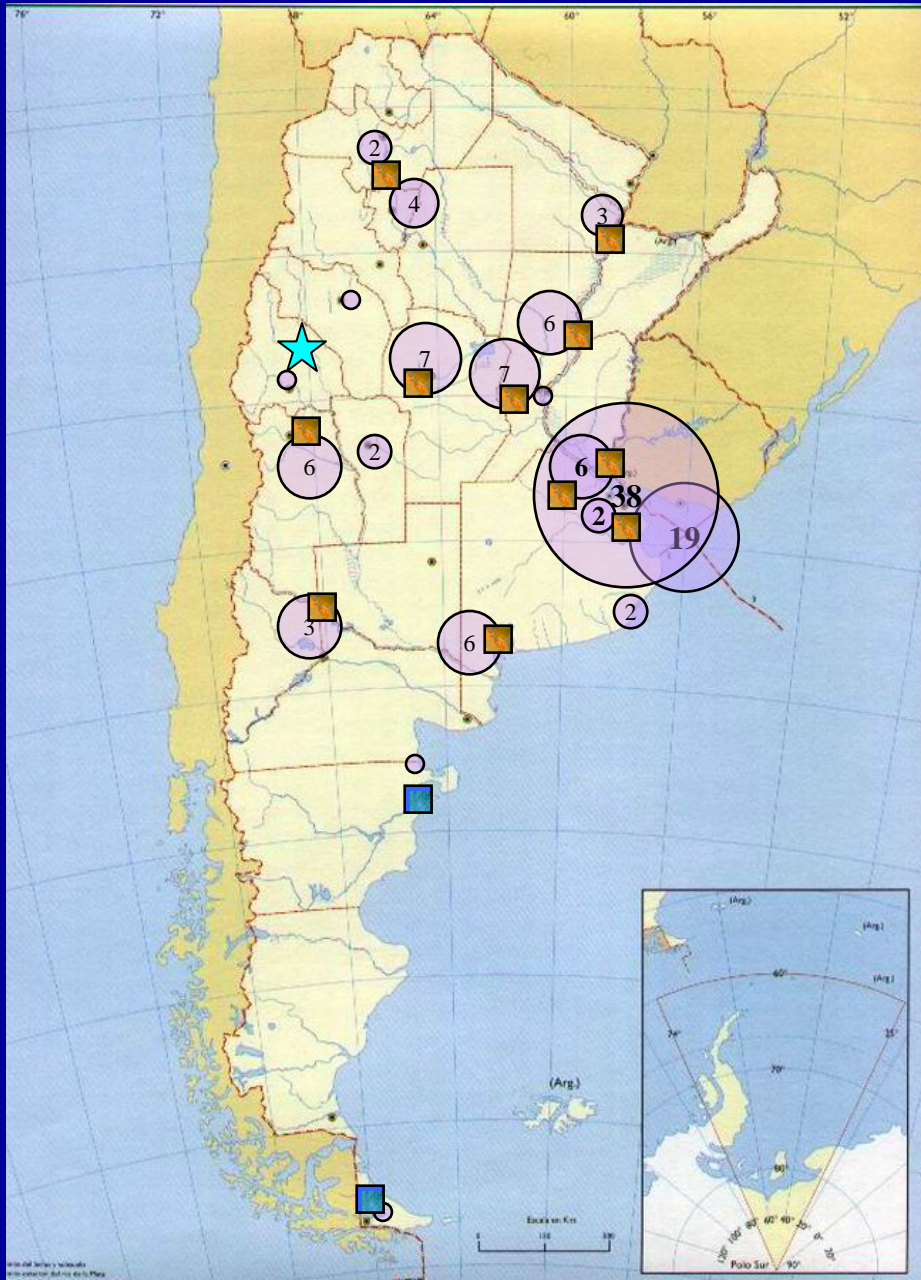
## Development of Biosafety regulations in Argentina




Susana Fink, PhD

CONICET and

Academia Nacional de Medicina de Buenos Aires

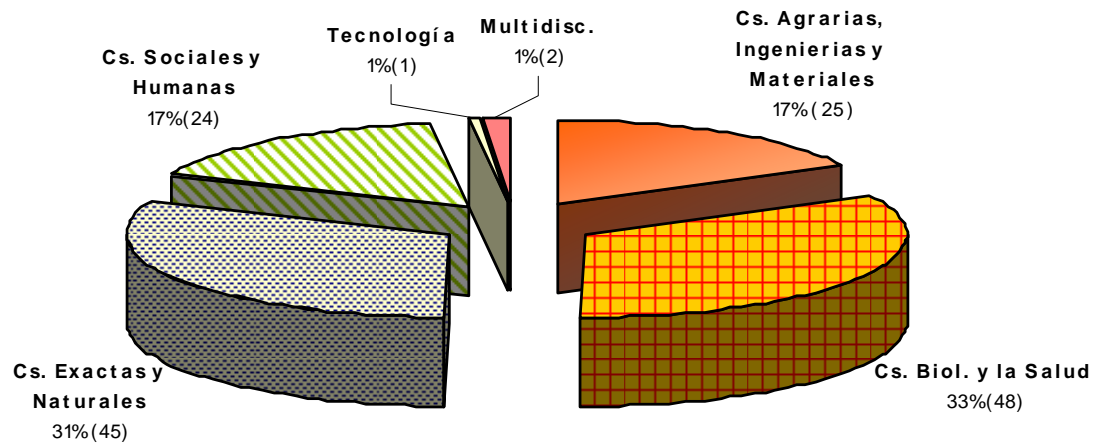
Argentina



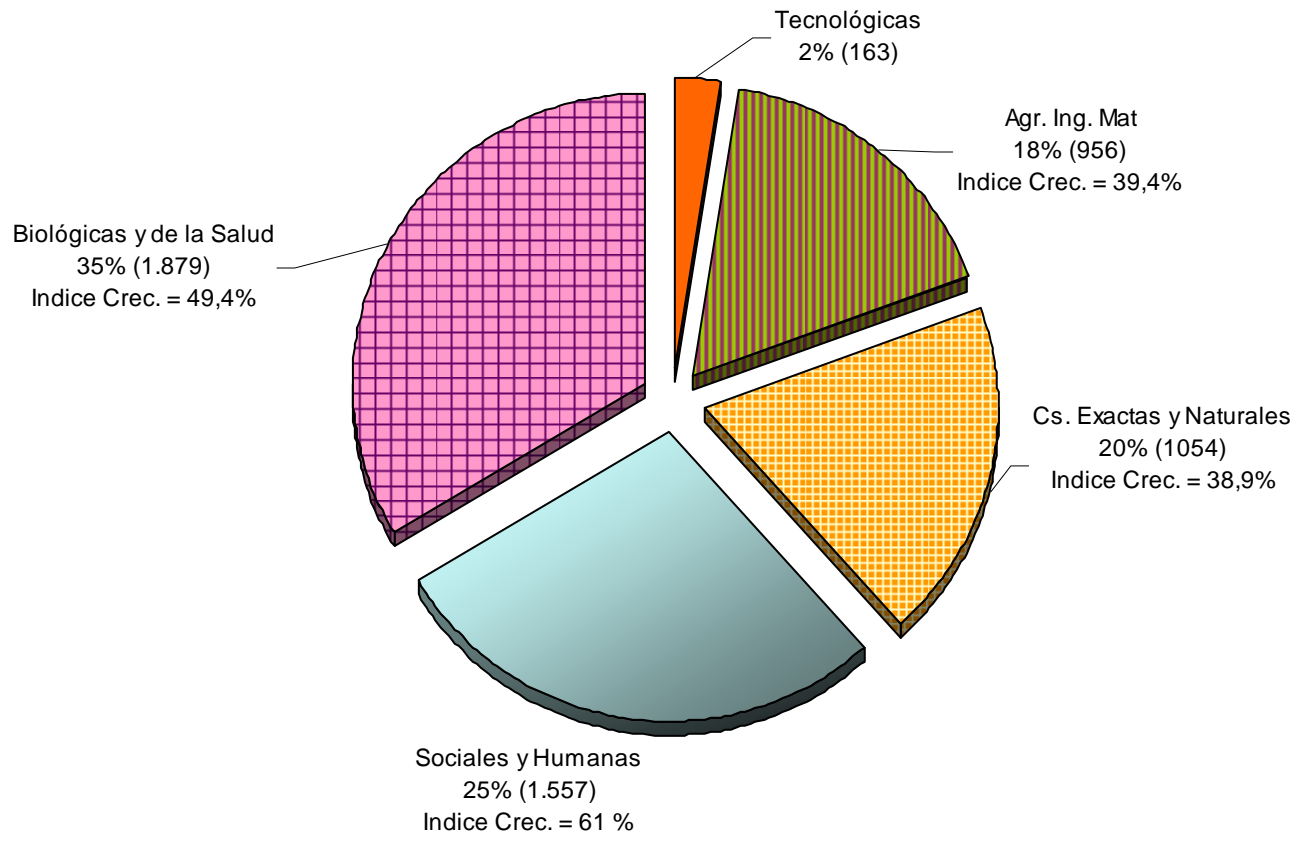
-  S&T Regional Centers
-  Multidisciplinary Research Centers
-  Research Units

5000 Full time researchers  
 5500 Doctoral and postdoctoral fellows  
 2000 professional technicians  
 120 Research Units  
 1500 Research projects

**CONICET**  
**Research units system**  
**Number of work units according to Great area of knowledge**  
**Total : 145 units**



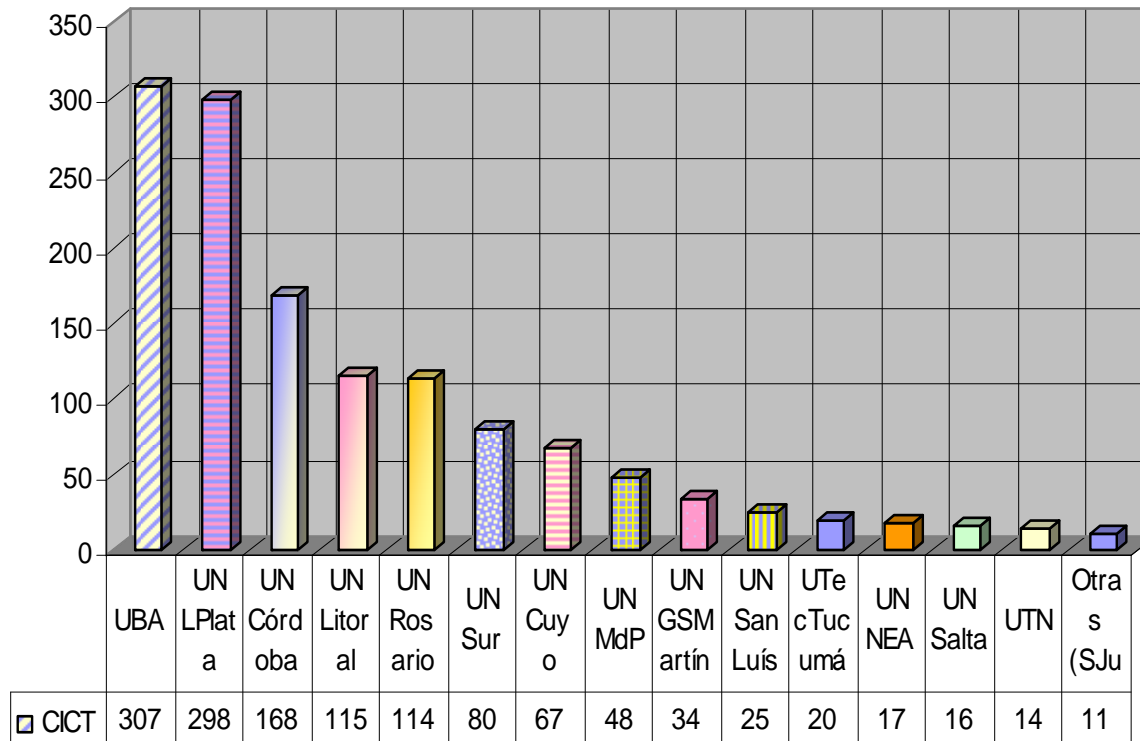
**CONICET  
Fellowships**  
Distribution according to Great area of knowledge  
Total: 5609 / Dec-2007  
Growth index 04-07 = 48%



## CONICET

### Researchers working in units with agreements with National Universities

Total : 1334 (December 2007)



# CONICET:

*Area: Biological and Medical Sciences*

Medicine	1703 Researchers
Biology	1882 Fellows
Biochemistry	709 Technicians
Veterinary Medicine	4294 Total

December 2007

# Background

The National Council for Scientific and  
Technological Research of Argentina  
(CONICET)



2004 Training program on basic Chemical and Biological  
Safety

2005 Occupational Health and Safety specialist

2006 Occupational Health MD

2006 Occupational Safety, Biosafety and Quality Committee

# Background



2007 Strategy approved

Vision:

*A trustable CONICET in its activities and results.*

# Background



2007 Strategy approved

Objective: *To reach*

- *Occupational Health and Safety, and Biosafety conditions for CONICET members and third parties in work places under CONICET jurisdiction*
- *Warranty of respect or improvement of the environment*
- *Intrinsic quality in practices and results of research, development and services.*

# Courses-Training

- Academia Nacional de Medicina (since 2002).
- Universidad Nacional de Mar del Plata (postgraduate course. 2006, 2007).
- Universidad de Buenos Aires (update course for OSHS, 2006).
- Universidad Nacional de Rosario (postgraduate course, mandatory for postgraduate students in biomedical areas since 2008).

# Legal Background



- National Law 19587/72,  
Occupational Hygiene and Safety Law, and  
explanatory regulations and modifications.
- National Law 24557/95,  
Occupational Risks Law.

# Legal Background

Occupational Hygiene and Safety Law, and explanatory regulations and modifications.

- Thermal load
- Chemical contamination
- Lighting
- Noise and vibrations
- Electrical installations
- Fire protection
- Ergonomics and weight lifting
- Radiation (ionizing and not ionizing)

# Legal Background

Occupational Hygiene and Safety Law, and explanatory regulations and modifications.

- Technical rules and sanitary measures to protect life, maintain psychophysical integrity of workers, prevent, reduce, isolate or eliminate risks, stimulate accident prevention as well as prevention of occupational illness.
- Establishes responsibilities for employers and employees.
- Equipment and tools
- Lifting equipment, etc

# Legal Background

Occupational Hygiene and Safety Law, and explanatory regulations and modifications.



Main scope



**INDUSTRY**

# Legal Background



Occupational Hygiene and Safety Law, and explanatory regulations and modifications.

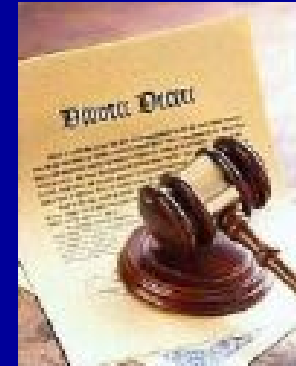
*Regulations for occupations with particular risks:*

- ❖ Construction industry (Decree 911/96)
- ❖ Agricultural activities (Decree 617/97)
- ❖ Mining activities (Decree 249/07)

# Legal Background

National Law 24557/95

Occupational Risks Law.



- ❖ Accidents at the workplace (Definiton of accident)
- ❖ Accidents while commuting ("in itinere")
- ❖ Occupational illnesses (Definition, Open list, includes many infections)

**Creates insurance companies (ARTs) and a supervising agency (SRT)**

# Legal Background



## *Other laws with subjects related to Biological Safety*

- National law 23798 (AIDS law).
- National law 22990 and Resolution 58/05 (Blood law, includes cord blood).
- National law 24151 (HepB vaccination mandatory for HCW).

# Legal Background



*Other laws with subjects related to Biological Safety*

- **Biotechnology regulatory frame (CONABIA) and Biotechnology promotion law 26270/07.**
- **National law 24051. (Dangerous wastes law)**
- **Laws and consensus on transportation of dangerous goods.**

# Legal Background



Ministry of Health: Specific regulations

SARS

BBP

Biosafety regulations for health care institutions

Avian flu

Sterilization and disinfection guidelines

Anthrax



WHA 58.29/05

Increase biological safety in  
laboratories

CONICET proposal to SRT

TO GENERATE SPECIFIC REGULATIONS  
FOR BIOLOGICAL RISK

Ministry of Health  
ANLIS Malbrán

# SPECIFIC REGULATIONS FOR BIOLOGICAL RISK



➤ The above mentioned laws apply but more stringent specific regulations are required.

➤ The Spanish Real Decreto 664/1997.

*Protection of workers from risks related to exposure to biological agents at work.*

➤ Adapt to Argentine needs and realities.

# Scope



- Workers in both human and animal biomedical and biochemical areas with recognised risk if exposed to biological agents.
- Other workers that may be exposed to biological, allergenic or toxic risk, even if it is not the cause or object of their work (anthropologists, archeologists, speleologists, etc).

# Risk identification and assessment

- According to agent and activity.
- Risks map
- Safe practices
- Known occupational illness
- Risk for sensitive personnel
- Contention measures
- Collective protection elements
- Personal protection elements



# Agent substitution



- Substitution for agents presenting lower risk is recommended.

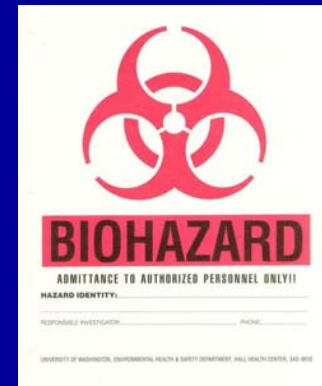
# Risk reduction



- Contention
- Reduce number of workers exposed
- Safe measures for reception, manipulation and transportation of biological agents at the work place
- Collective protection measures
- Personal protection measures
- Waste management

# Risk reduction

- Hygiene measures in order to avoid scattering outside of the work area
- Biological risk Signage
- Accident contingency plan
- Special protection measures for workers with special requirements.



# Good laboratory practices

- ❖ Eating, drinking, smoking and mouth pipetting forbidden.
- ❖ Appropriate clothing
- ❖ Adequate washrooms and changing rooms.  
Availability of antiseptic soap.
- ❖ Adequate storage of PPE
- ❖ Appropriate cleaning and maintenance of all protection elements

# Good laboratory practices



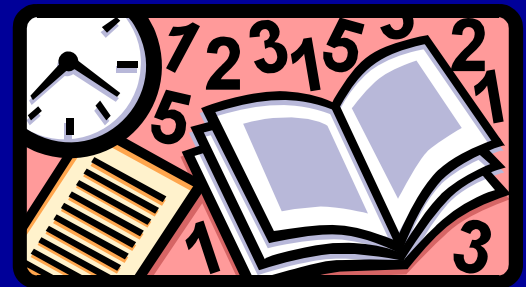
- Provision of washing, decontamination or destruction of clothing
- Adequate packaging of dirty clothing
- Cost covered by employer

# Health surveillance

- Periodical check ups according to the risk
- Check ups when an infection or disease is detected in another worker with similar exposure.
- Trained medical staff.
- Personal medical history
- Reports

# Accidents and incidents

- **Report** and **recording** systems for both accidents and near accidents are required.



# Documents

- Results of risk assessment, criteria, procedures, measurement or assay methods.
- List of workers exposed to biological risk agents, type of work and agent, and their registered exposures, accidents or incidents.
- In special situations a prolonged time for keeping records.

# Authorities notification

- For agents of the higher risk groups notification is required prior to start working.
- For diagnostics labs only at starting time.
- New notification if major changes are introduced

# Information to authorities

The employer must provide

- Results and details of the assessment to the occupational and health authorities.
- Activities that cause or may cause exposure.
- Number of exposed workers
- Name and training of prevention responsible.
- Prevention and protection measures adopted
- Emergency /contingency plan

# Information to authorities

The employer must provide

- Immediate report in case of
  - accident
  - occupational illness
  - death

# Workers training and information

- Workers informed about any health and safety protection measure.
- Workers adequately trained.
- Workers informed about
  - potential health risks
  - precautions to avoid exposure
  - hygiene measures
  - use of clothing and PPE
  - accident and/or incident response.

# Workers training and information

- Workers training when
  - ❖ Changes in activities
  - ❖ New risks
  - ❖ Written instructions at work place, written procedures.
  - ❖ Accident report: immediate from worker to superior and from employer to workers.

# Training and continuous education

- *General in Biosafety*
- *Specific for the required task*

# Special measures

- For sanitary and veterinary establishments, not in research or diagnostics.
- For research labs and places with animal experimentation.

# Annexes: Classification of biological risk agents



- Includes autoctonous species.
- Takes into account activity performed.
- List and classification periodically updated.

# Annexes:

## Matrix for risk assessment



- Position (from professionals to visitors)
- Practices
- Equipment
- Personal protection elements
- Immune prophylaxis
- Training
- Infrastructure

# Annexes

## Personal protection elements

### Specifications for

- Clothing
- Respiratory protection
- Ocular/facial protection
- Gloves

# Issues to be solved

- ❖ There are *no national standards* for personal protection elements
- ❖ There are *no national standards* for BSCs.
- ❖ Formal training in Biosafety.

❖ To avoid accidental dissemination

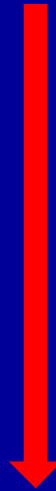
**(Biosafety)**

❖ Prevent possible intentional dissemination

**(Biosecurity)**

- REGULATIONS

- AWARENESS



- Improvement of workers and community health and safety

- Sergio Miguel

Ministry of Health, ANLIS Malbrán

- Claudio Sanjuan, SRT

- Omar Metallo, CONICET

- Jorge Tezón, CONICET



Gracias por su atención!