

# Technology for the management of Biosafety

**Authors:** PhD. Dailin Cobos Valdes  
PhD. Mayra Ramos Lima  
PhD. Carlos Manuel Vilariño Corella  
PhD. Osmir Cabrera Blanco  
PhD. Antonio Torres Valle

Centro de Immunología y Biopreparados  
Holguín, Cuba

[cibho@cibho.hlg.minag.cu](mailto:cibho@cibho.hlg.minag.cu)



***Current affiliation:***

Diagnostics Biochem Canada Inc.

London, Ontario

[dbc@dbc-labs.com](mailto:dbc@dbc-labs.com)

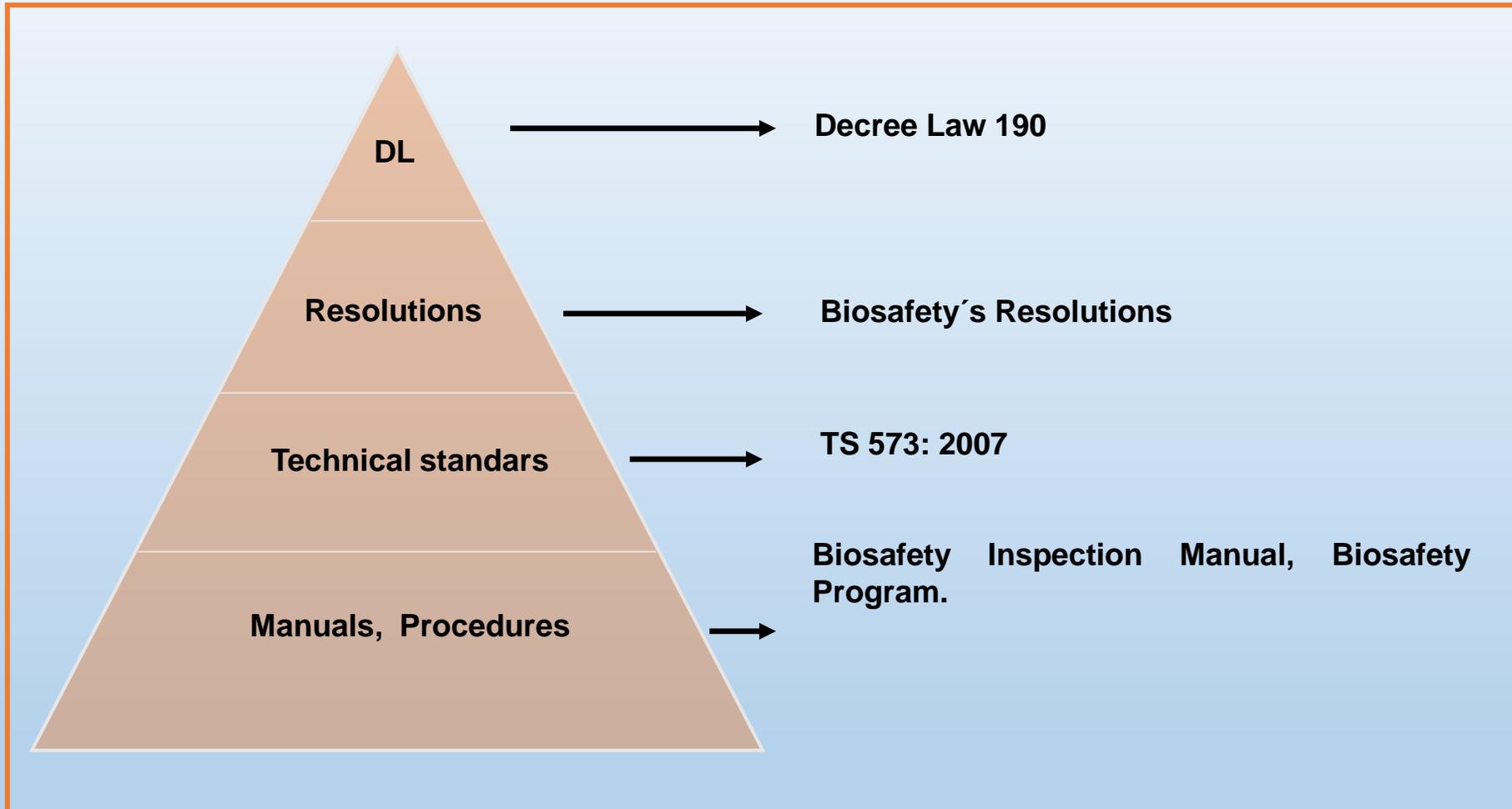


# Background

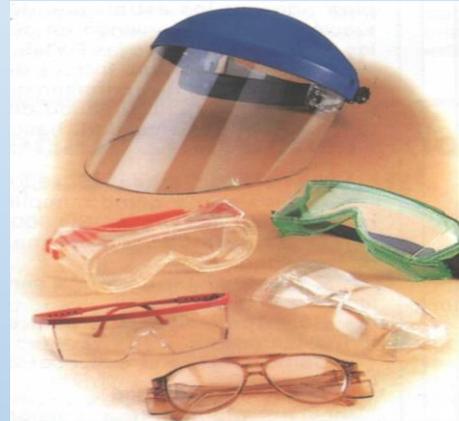
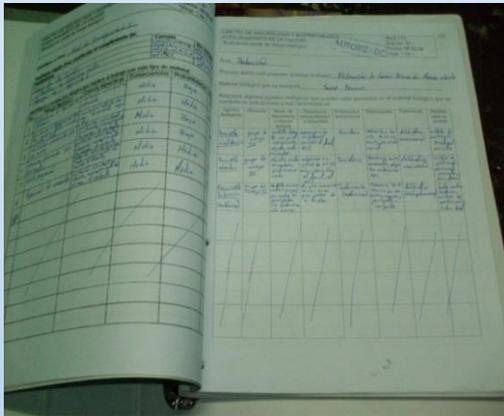
**Biosafety**



Set of scientific-organizational and technical-engineering measures designed to protect the worker of the facility, the community and the environment from the risks involved in working with biological agents, or the release of organisms into the environment, minimize the effects that may arise and quickly liquidate their possible consequences in case of contamination, adverse effects, escapes or losses ( Decree Law 190, 1999).



## Basic Requirements



teaching, research, biotechnology

Torres and Carbonell (2013), Nisii *et al.* (2013), Carvalho *et al.* (2013)

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**Biosafety  
management**

**Risks  
assessment**

**Biosecurity**

**Handling  
and disposal  
of hazardous**

**Culture of  
Biosafety**

**Training**

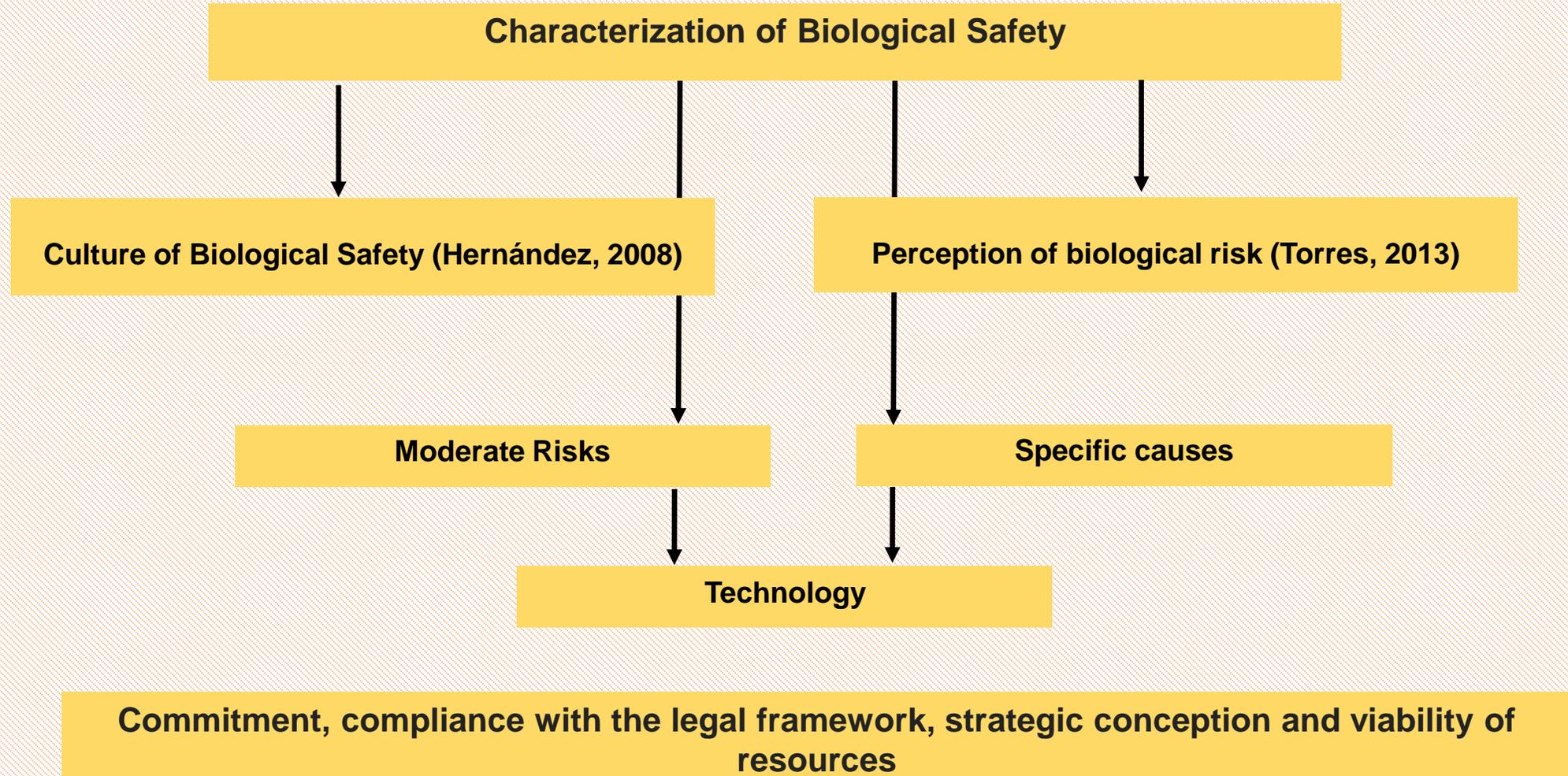
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# **Main goal**

To develop a technology for the organization of Biological  
Safety

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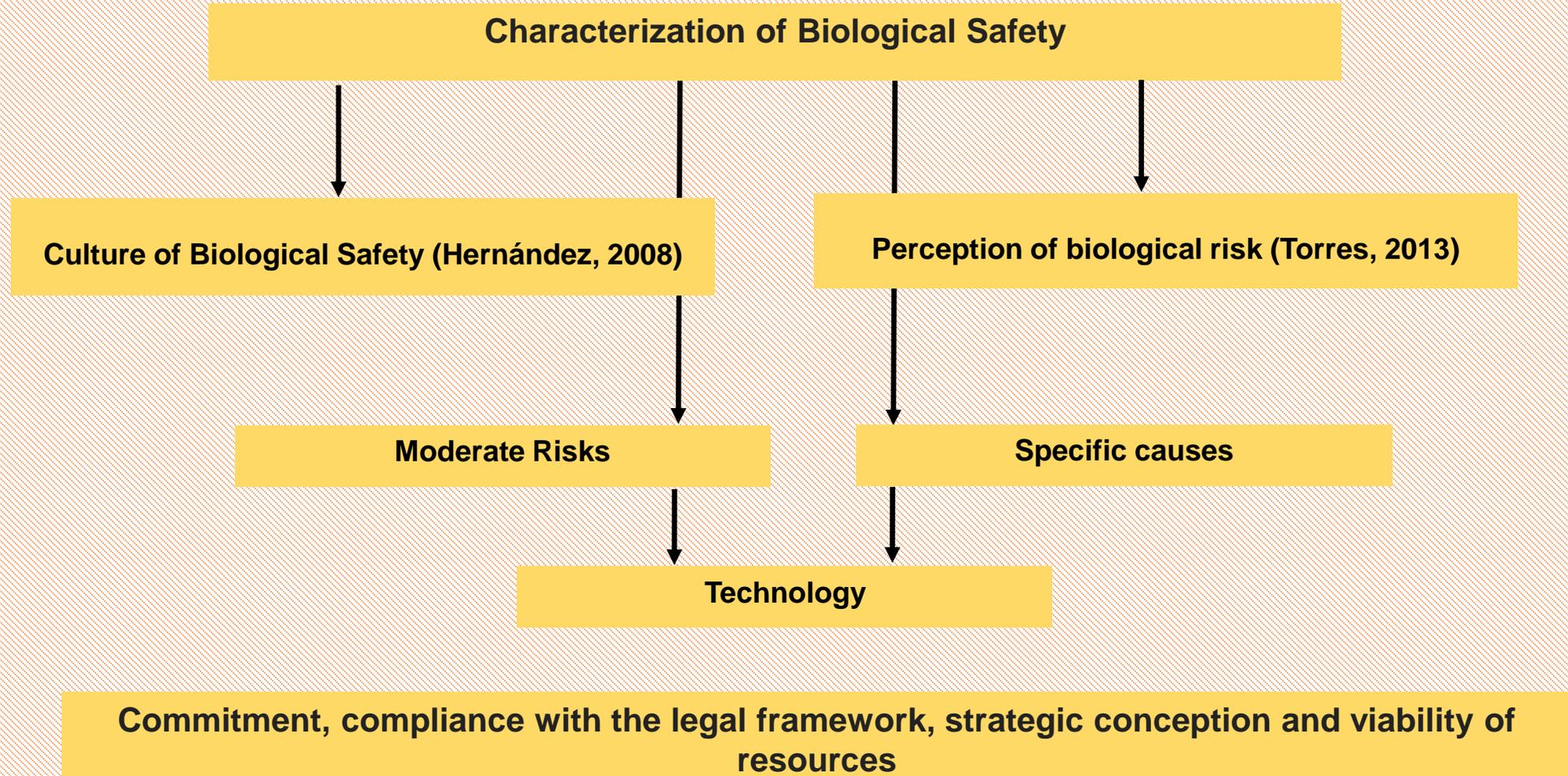
# Materials and Methods



Variable	Questions	Possible answers
<b>1. Related with the individual</b>		
<b>Familiarity</b>	<b>1. Have you received basic training on Biological Safety? (Q1)</b>	<b>No/very little/ enough</b>
	<b>2. How long you have been in this job? (Q2)</b>	<b>1 year, 1 a 5 years, more than 5 years</b>
	<b>3. Have you received specific training related with biological risk in this job? (Q3)</b>	<b>No/very little/ enough</b>

31 questions  
7 experts,  
competence  
coefficient  
between 0.8 -  
1

# Materials and Methods



CIBHO: From September 2008 to September 2010



CIRAH: From January 2012 to September 2014



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# **Results and Discussion**

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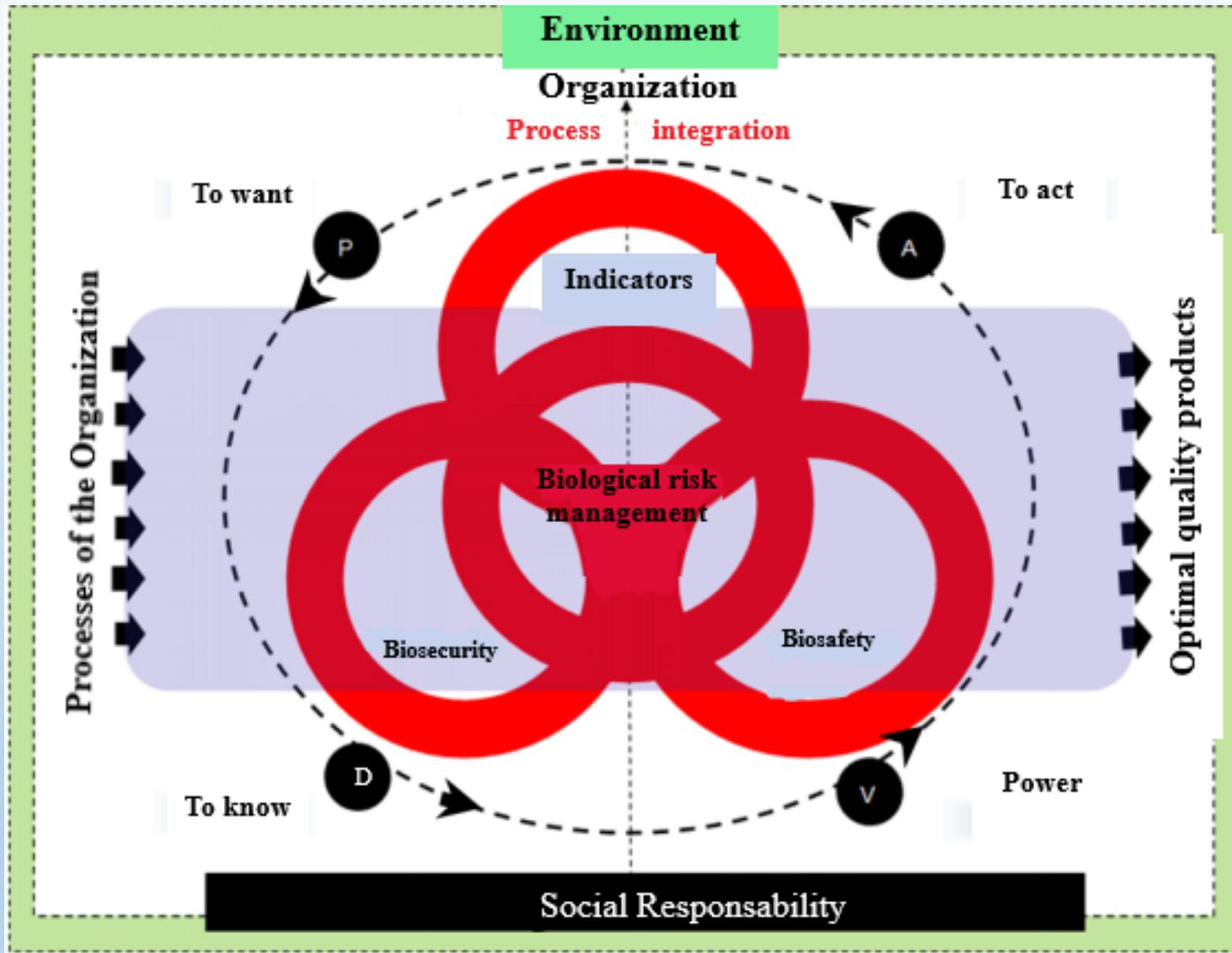


Figure 1. Conceptual model for the organization of Biological Safety

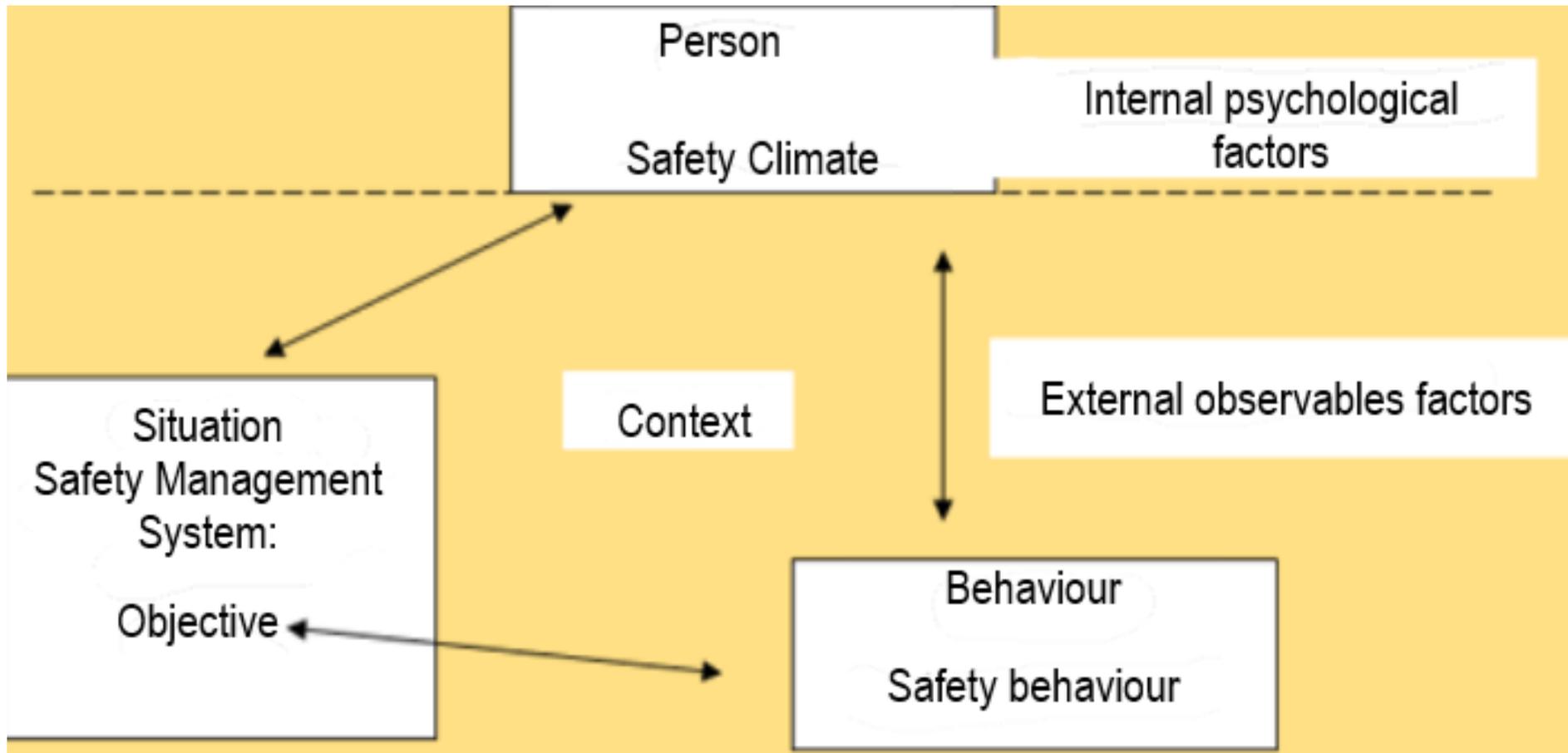


Figure 2. Conceptual model by Cooper, 1995

# Procedure

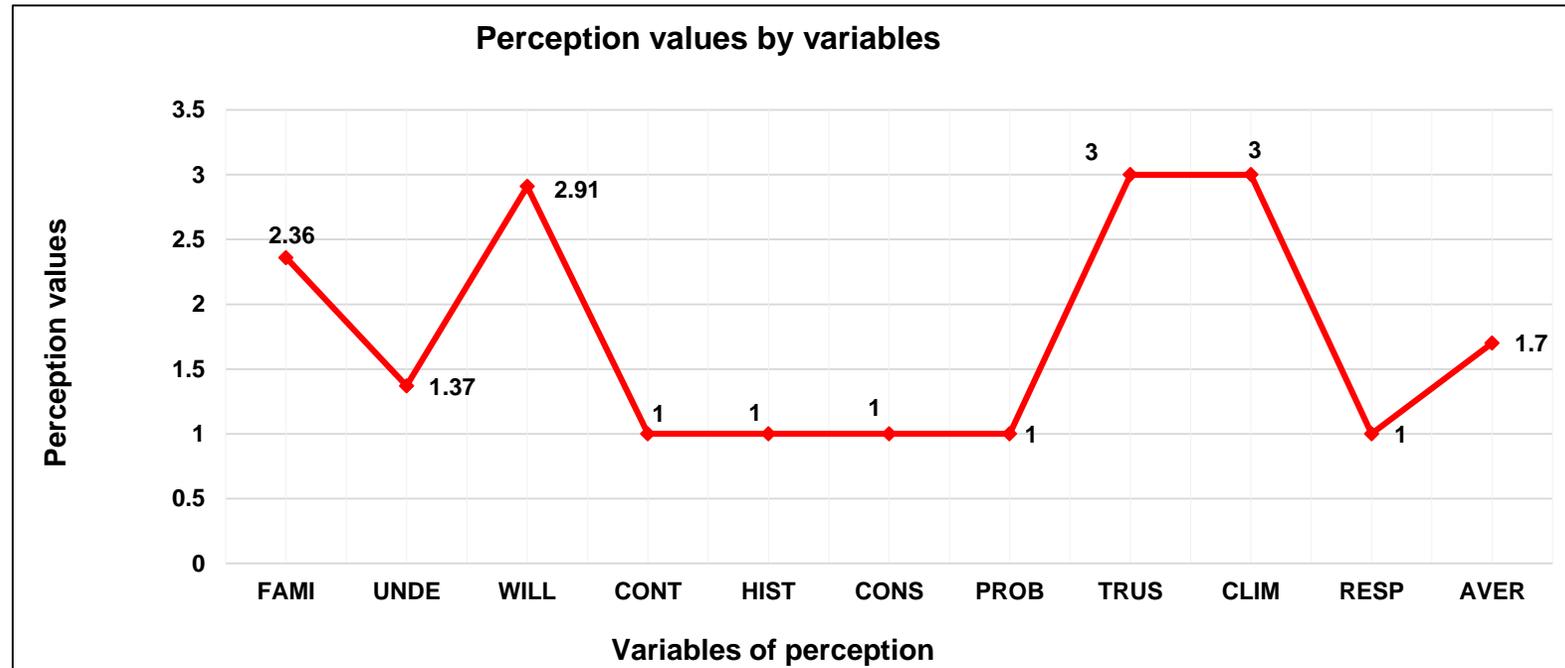
<b>Characterization of Biological Safety</b>	<b>Organization of Biological Safety and Biosecurity</b>	<b>Application of Biological Safety's documentation</b>	<b>Technology evaluation through the analysis of indicators</b>
<ol style="list-style-type: none"><li>1. Selection of indicators</li><li>2. Analysis of indicators</li></ol>	<ol style="list-style-type: none"><li>1. Definition of Biological Safety policy</li><li>2. Organization chart of Biological Safety</li><li>3. General procedures of Biological Safety</li><li>4. Specific procedures of Biological Safety</li></ol>	<ol style="list-style-type: none"><li>1. Implementation of Biological Safety's documents</li><li>2. Staff evaluation</li></ol>	

# Characterization of Biological Safety in CIBHO

Table 1. First Qualification. Aspects and Culture of Biological Safety

<b>Aspects</b>	<b>Management status</b>	
	<b>Quantitative</b>	<b>Qualitative</b>
<b>1. Policy</b>	<b>2,65</b>	<b>Fragile</b>
<b>2. Organization chart of Biological Safety</b>	<b>3,12</b>	<b>Adequate</b>
<b>3. Materials resources</b>	<b>2,24</b>	<b>Fragile</b>
<b>4. Self-regulation</b>	<b>3,71</b>	<b>Adequate</b>
<b>5. Definition and Control</b>	<b>2,59</b>	<b>Fragile</b>
<b>6. Responsibilites</b>	<b>3,71</b>	<b>Adequate</b>
<b>7. Training</b>	<b>2,65</b>	<b>Fragile</b>
<b>8. Premium and sanctions</b>	<b>1,12</b>	<b>Unsafe</b>
<b>9. Audit, exam and comparison</b>	<b>3,76</b>	<b>Adequate</b>
<b>10. Critical attitude</b>	<b>2,35</b>	<b>Fragile</b>
<b>11. Rigorous approach</b>	<b>2,29</b>	<b>Fragile</b>
<b>12. Communication</b>	<b>2,82</b>	<b>Fragile</b>
		<b>Developing</b>
<b>Culture of Biological Safety</b>	<b>2,75</b>	

## Initial perception of biological risk: 1,7



FAMI: Familiarity, UNDE: Understanding of risk, WILL: Willfulness, CONT: Controlability, HIST: Accident history, CONS: Immediate consequences, PROB: Estimate of the probabilities, TRUS: Trust in institutions, CLIM: Organizational climate, RESP: Response from supervisors. AVER: Average

Figure 3. Perception of biological risk by variable and average in CIBHO

**Table 2. Number of risks assessed: 77 biological risks (22 moderate, 47 tolerable y ocho trivial)**

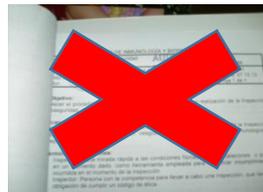
<b>Processes</b>	<b>Moderate risks</b>
Obtaining bovine blood	1
Obtaining hidrolizing material	2
Obtaining rabbit blood	3
Obtaining blood sheep	2
Scrubbing and treatment of glassware	7
Bovine blood sterility test	1
Sheep blood sterility test	1

## Specific causes

### Inadequate individual protection



### Breach of the rules of conduct

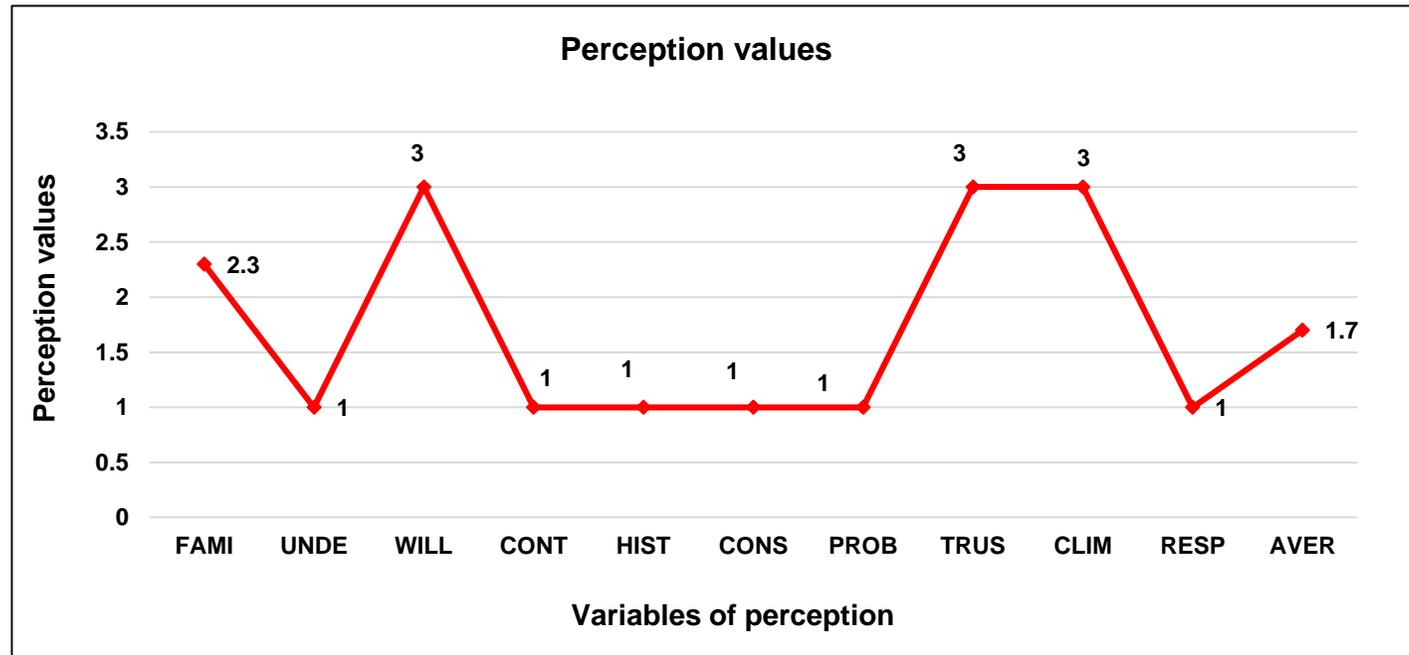


# Characterization of Biological Safety in CIRAH

Table 3. First Qualification. Aspects and Culture of Biological Safety

<b>Aspects</b>	<b>Management status</b>	
	<b>Quantitative</b>	<b>Qualitative</b>
<b>1. Policy</b>	<b>1,25</b>	<b>Unsafe</b>
<b>2. Organization chart of Biological Safety</b>	<b>1,83</b>	<b>Unsafe</b>
<b>3. Materials resources</b>	<b>1,75</b>	<b>Unsafe</b>
<b>4. Self-regulation</b>	<b>2</b>	<b>Fragile</b>
<b>5. Definition and Control</b>	<b>1,67</b>	<b>Unsafe</b>
<b>6. Responsibilités</b>	<b>1,92</b>	<b>Unsafe</b>
<b>7. Training</b>	<b>1,67</b>	<b>Unsafe</b>
<b>8. Premium and sanctions</b>	<b>1</b>	<b>Unsafe</b>
<b>9. Audit, exam and comparison</b>	<b>1</b>	<b>Unsafe</b>
<b>10. Critical attitude</b>	<b>2,83</b>	<b>Fragile</b>
<b>11. Rigorous approach</b>	<b>3,83</b>	<b>Adequate</b>
<b>12. Communication</b>	<b>3,08</b>	<b>Adequate</b>
<b>Culture of Biological Safety</b>	<b>1,99</b>	<b>Incipient</b>

## Initial perception of biological risk: 1,7



FAMI: Familiarity, UNDE: Understanding of risk, WILL: Willfulness, CONT: Controlability, HIST: Accident history, CONS: Immediate consequences, PROB: Estimate of the probabilities, TRUS: Trust in institutions, CLIM: Organizational climate, RESP: Response from supervisors. AVER: Average

Figure 4. Perception of biological risk by variable and average in CIRAH

**Table 4. Number of risks assessed: 42 biological risks (24 moderate, 13 tolerable and four trivial)**

<b>Processes</b>	<b>Moderate risks</b>
<b>Sampling</b>	<b>5</b>
<b>Isolation of DNA</b>	<b>9</b>
<b>Neurological studies</b>	<b>2</b>
<b>Scrubbing and treatment of glassware</b>	<b>8</b>

**Specific causes: Inadequate individual protection and breach of the rules of conduct**

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**Stage II. Organization of Biological Safety and Biosecurity with four steps:**

1. Definition of Biological Safety policy
  2. Organization chart of Biological Safety
-

# CIBHO

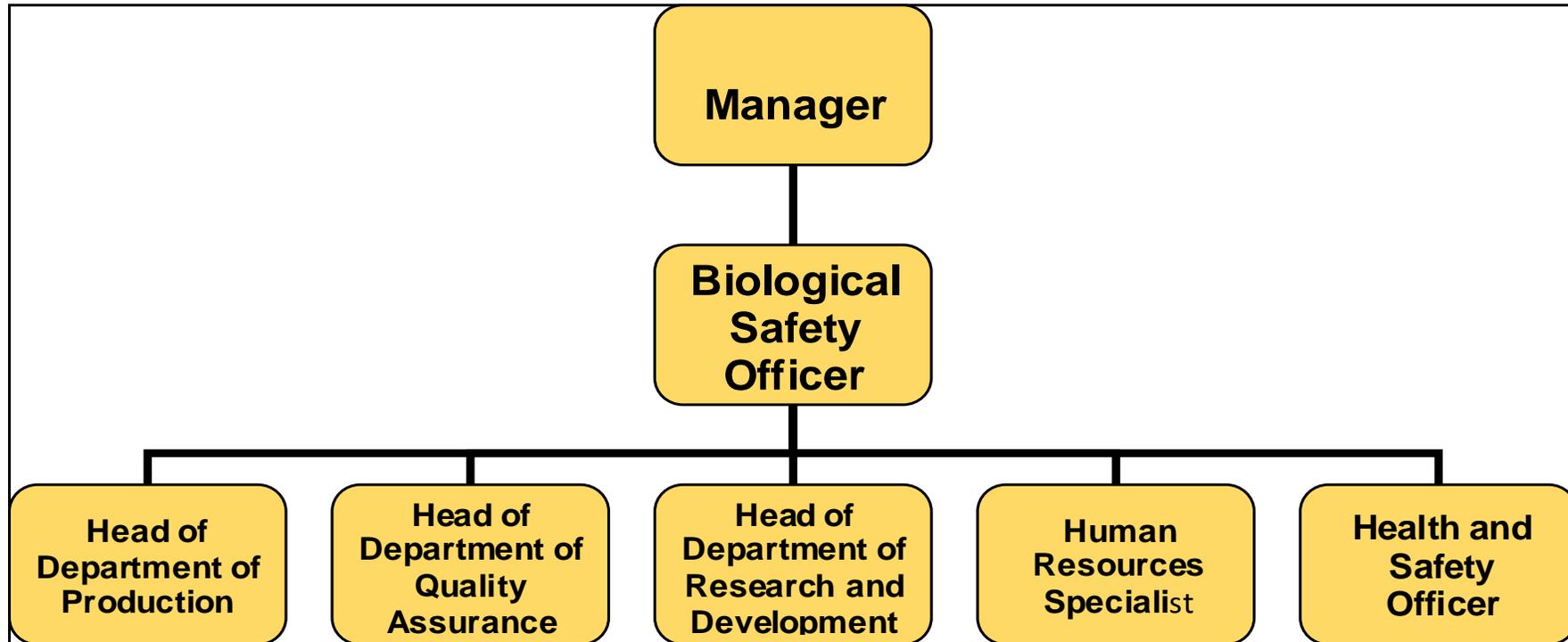


Figure 5. Organization chart Biological Safety in CIBHO

# CIRAH

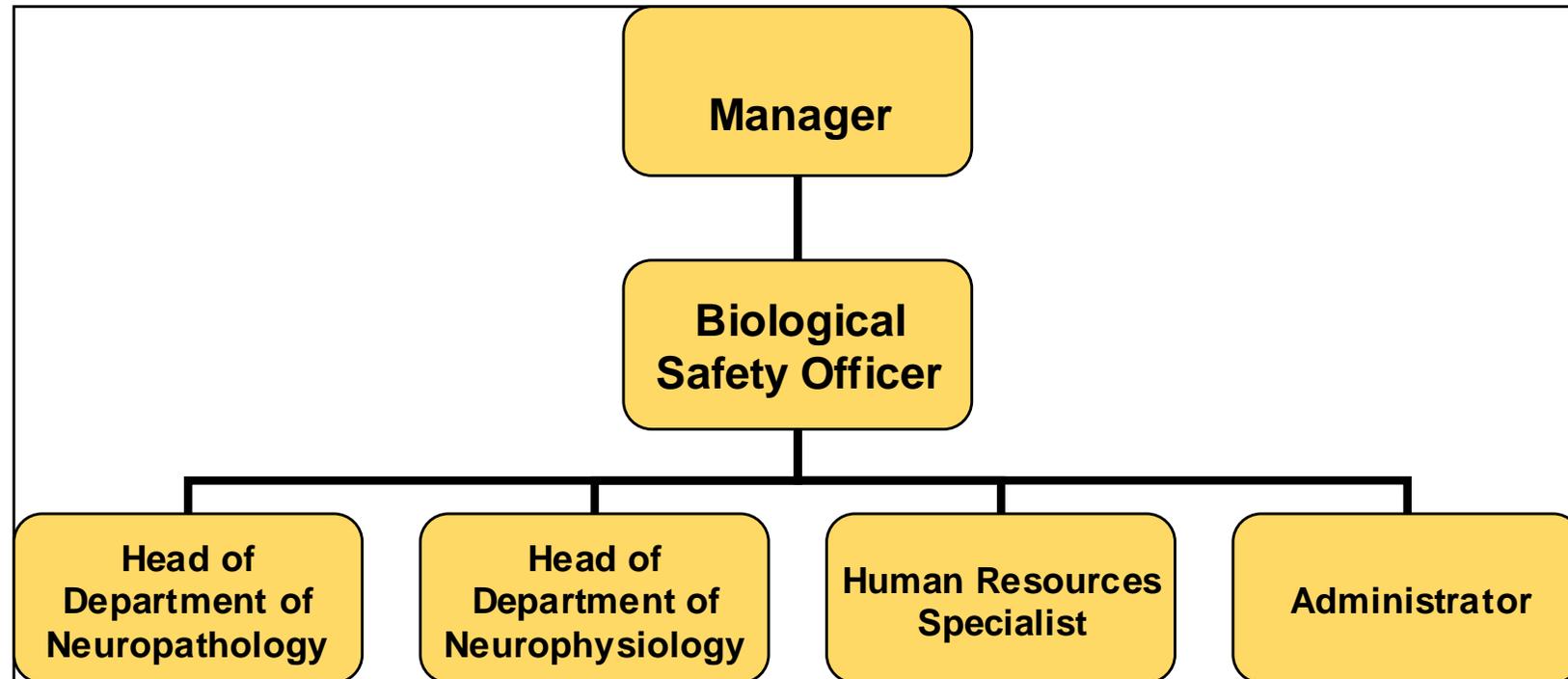


Figure 6. Organization chart Biological Safety in CIRAH

## **Stage II. Organization of Biological Safety and Biosecurity with four steps:**

### **3. General procedures of Biological Safety**

- Risk Assessment**
- Biological Safety Inspection**
- Emergency's procedures**
- Medical control of the Staff**
- Vector surveillance and control**
- Hazardous waste Management**
- Safety Standars: Biological Safety and Occupational Safety and Health Administration were integrated**

## **Stage II. Organization of Biological Safety and Biosecurity with four steps:**

### **4. Specific procedures of Biological Safety**

#### **CIBHO**

- Waste treatment and destructions**
- General use of equipments**
- Production´s Processes: disinfection, hazarodus waste, emergency management and safety measurements**

## **Stage II. Organization of Biological Safety and Biosecurity with four steps:**

### **4. Specific procedures of Biological Safety**

#### **CIRAH**

**Procedures for biological risk's processes: 39**

- Obtaining, receiving and transportation of samples**
- DNA Isolation**
- Storage, conservation and use of samples in DNA Bank**
- Processing and analysis of neurological tissues**

## Stage III. Application of Biological Safety's documentation and Biosecurity with two steps:

1. Implementation of Biological Safety's documents
2. Staff evaluation



**The score:**  
**CIBHO: 80 and more**



**CIRAH: 85 and more**

- **Stage IV. Technology evaluation through the analysis of the indicators**

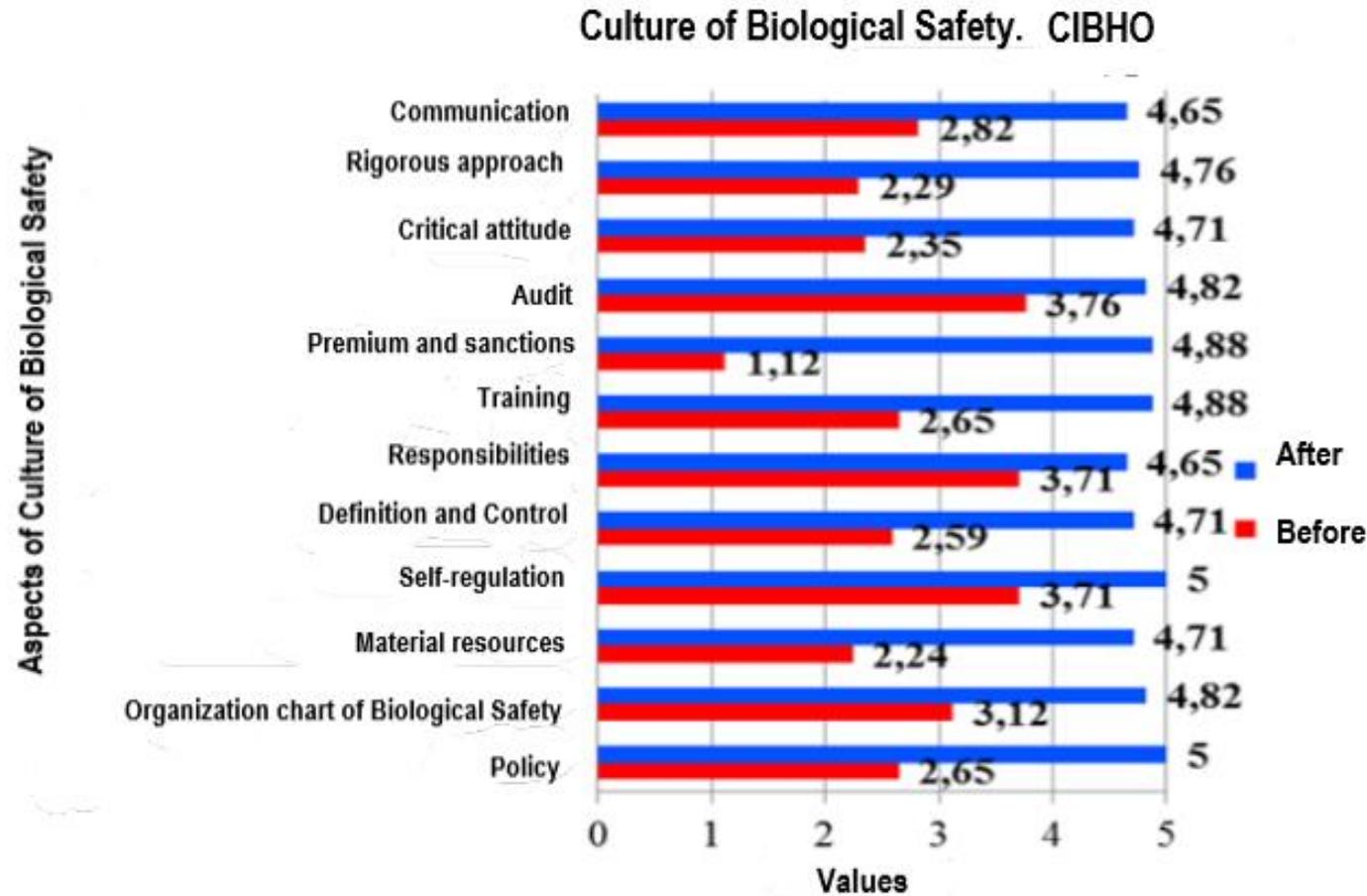


Figure 7. Comparison of the aspects of the Culture of Biological Safety. CIBHO. Before and after.

# Culture of Biological Safety. CIBHO: In development to Consolidated

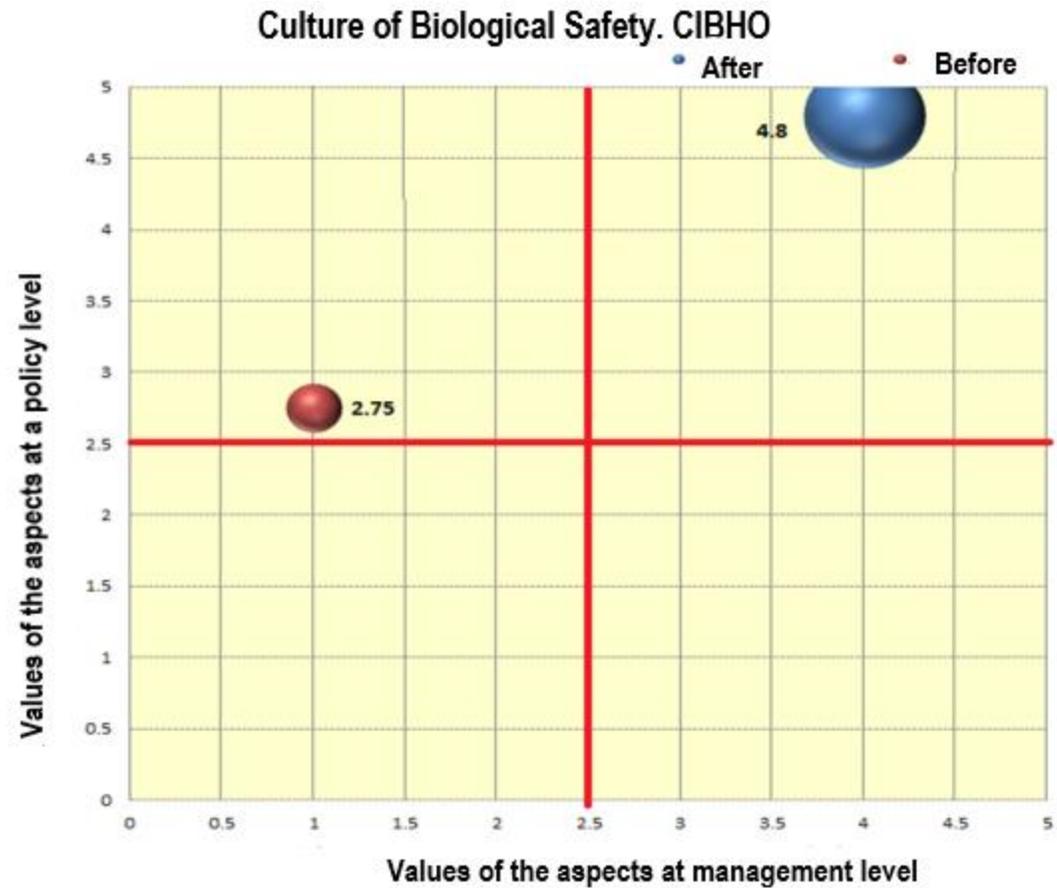
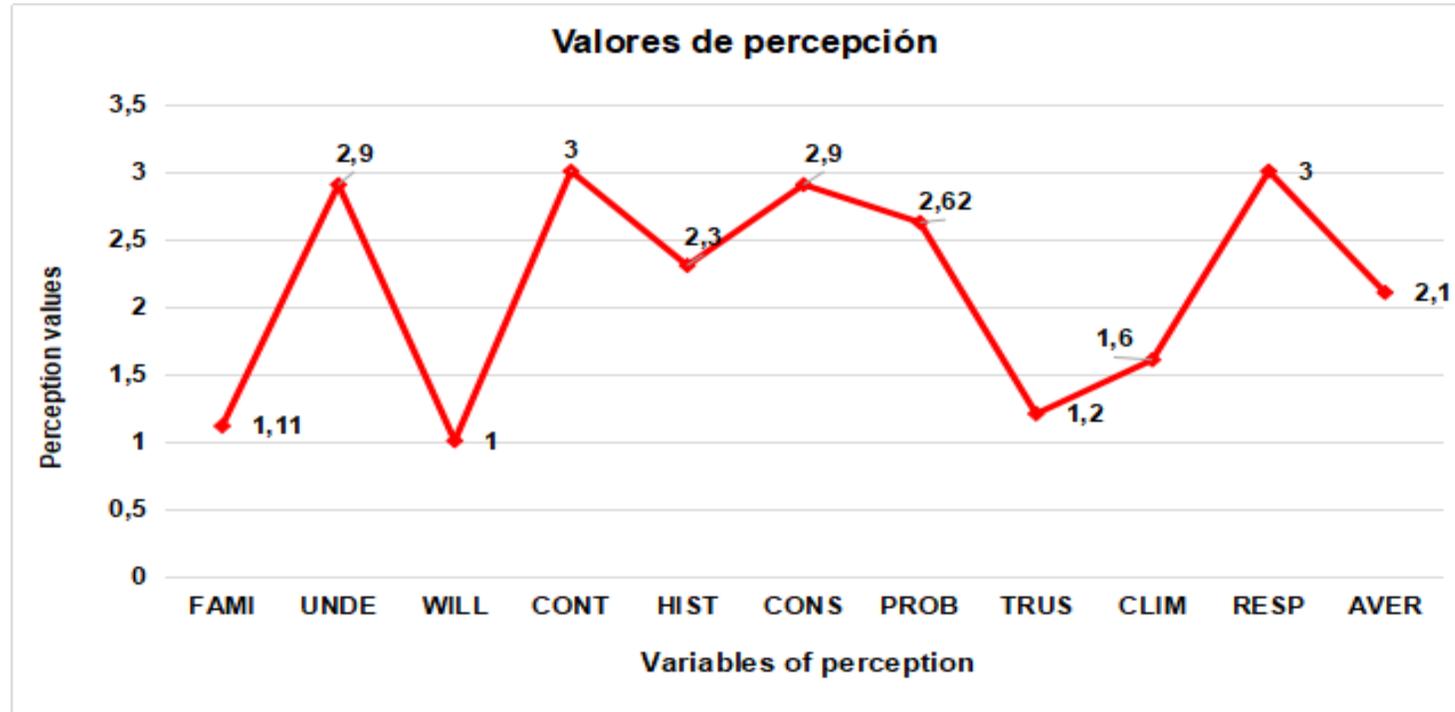


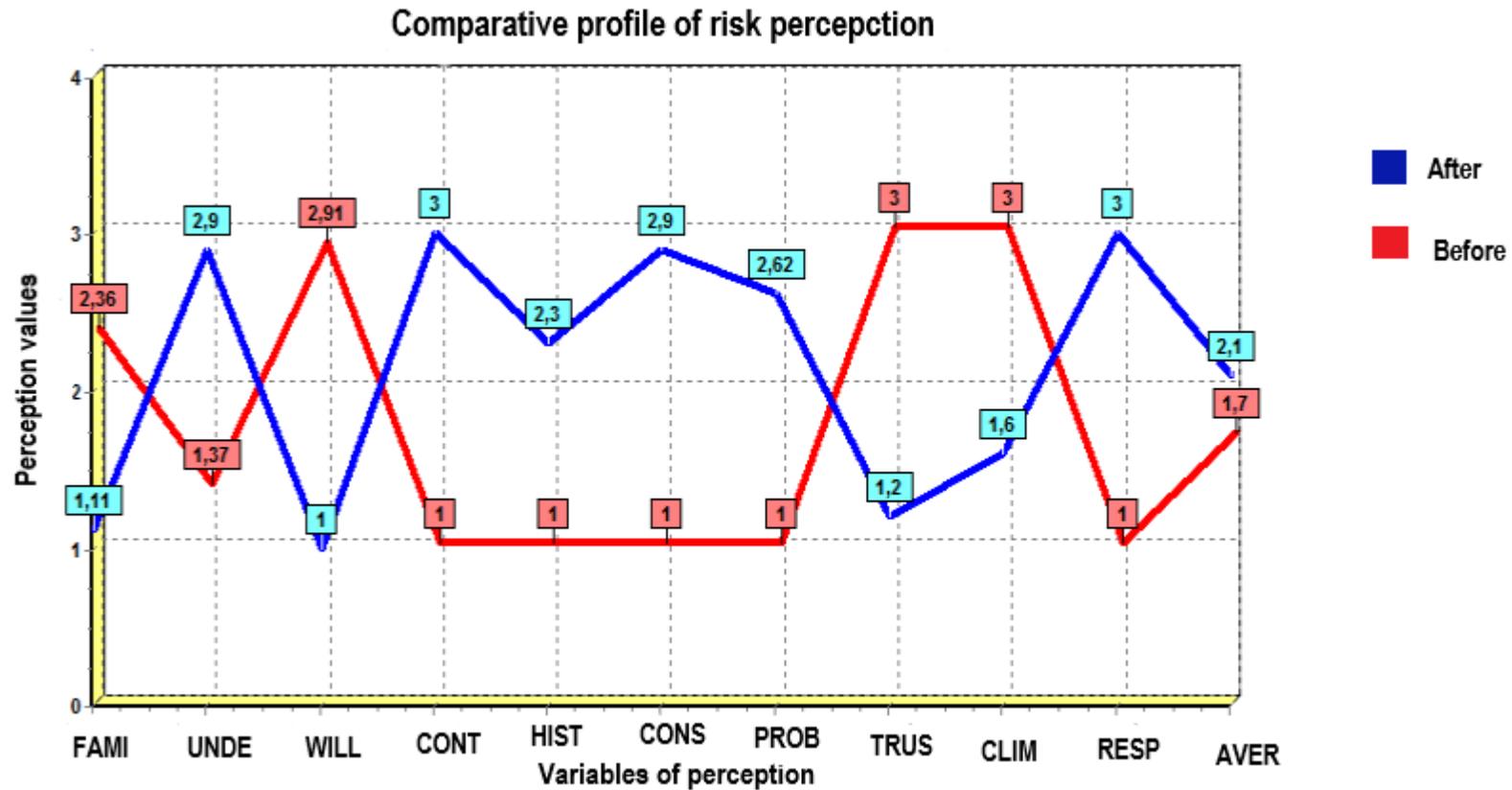
Figure 8. Matrix of the Culture of Biological Safety. CIBHO.

## Biological risk profile by perception variables once the technology is implemented. CIBHO



FAMI: Familiarity, UNDE: Understanding of risk, WILL: Willfulness, CONT: Controlability, HIST: Accident history, CONS: Immediate consequences, PROB: Estimate of the probabilities, TRUS: Trust in institutions, CLIM: Organizational climate, RESP: Response from supervisors. AVER: Average

Figure 9. Perception of biological risk by variable and average in CIBHO after the technology



FAMI: Familiarity, UNDE: Understanding of risk, WILL: Willfulness, CONT: Controlability, HIST: Accident history, CONS: Immediate consequences, PROB: Estimate of the probabilities, TRUS: Trust in institutions, CLIM: Organizational climate, RESP: Response from supervisors. AVER: Average

Figure 10. Perception of biological risk by variable and average in CIBHO before and after the technology

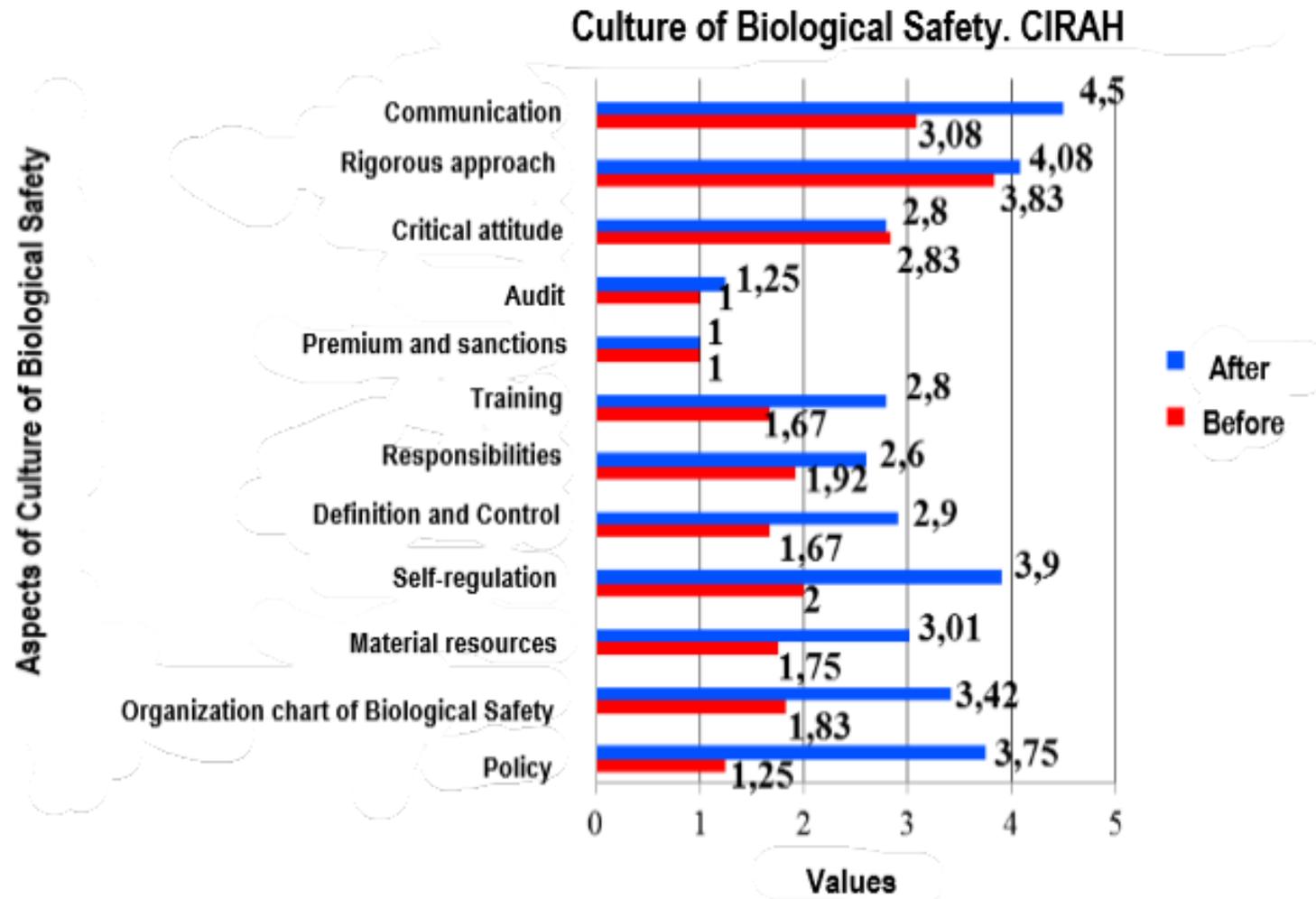


Figure 11. Comparison of the aspects of the Culture of Biological Safety. CIBHO. Before and after.

## Culture of Biological Safety. CIRAH: Incipient to On take off

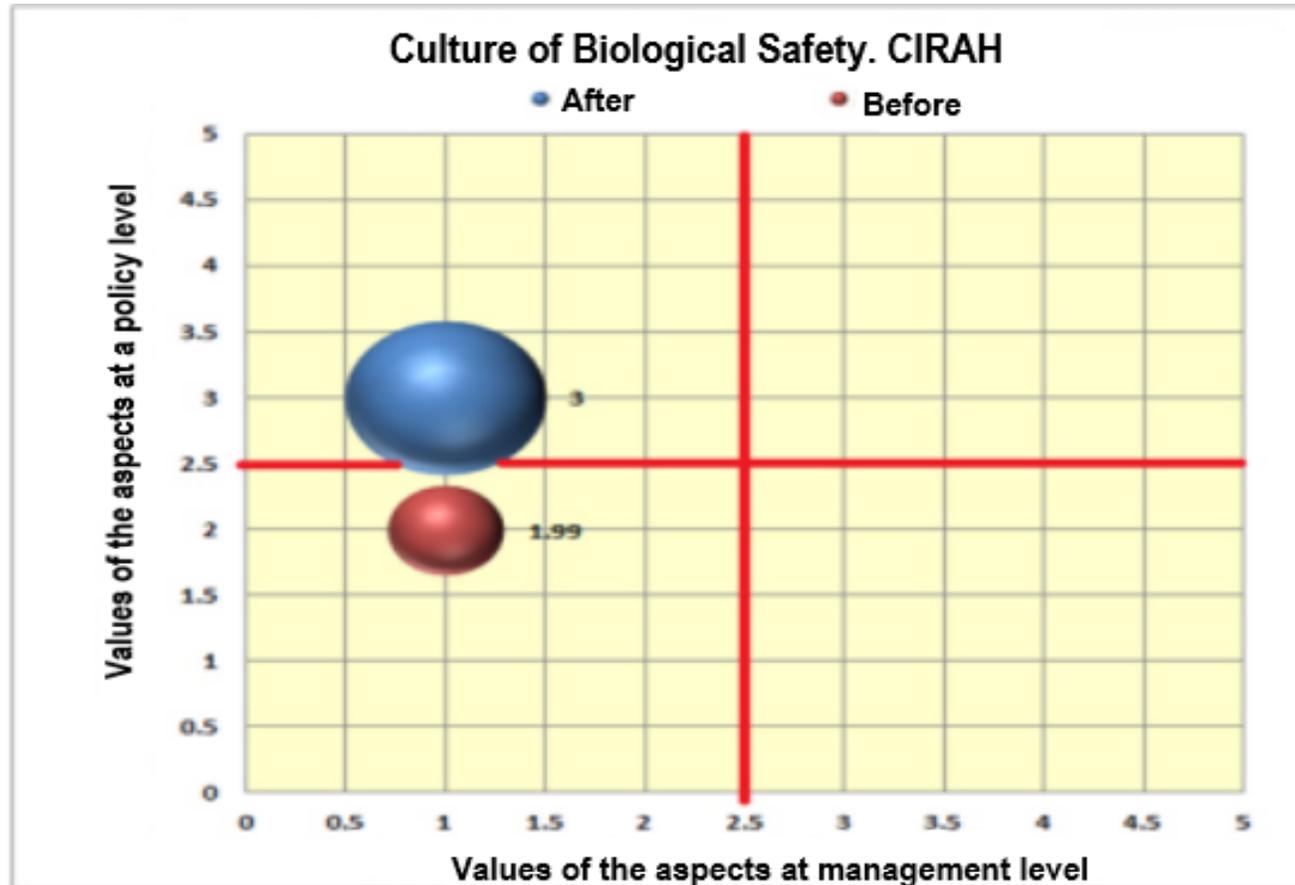
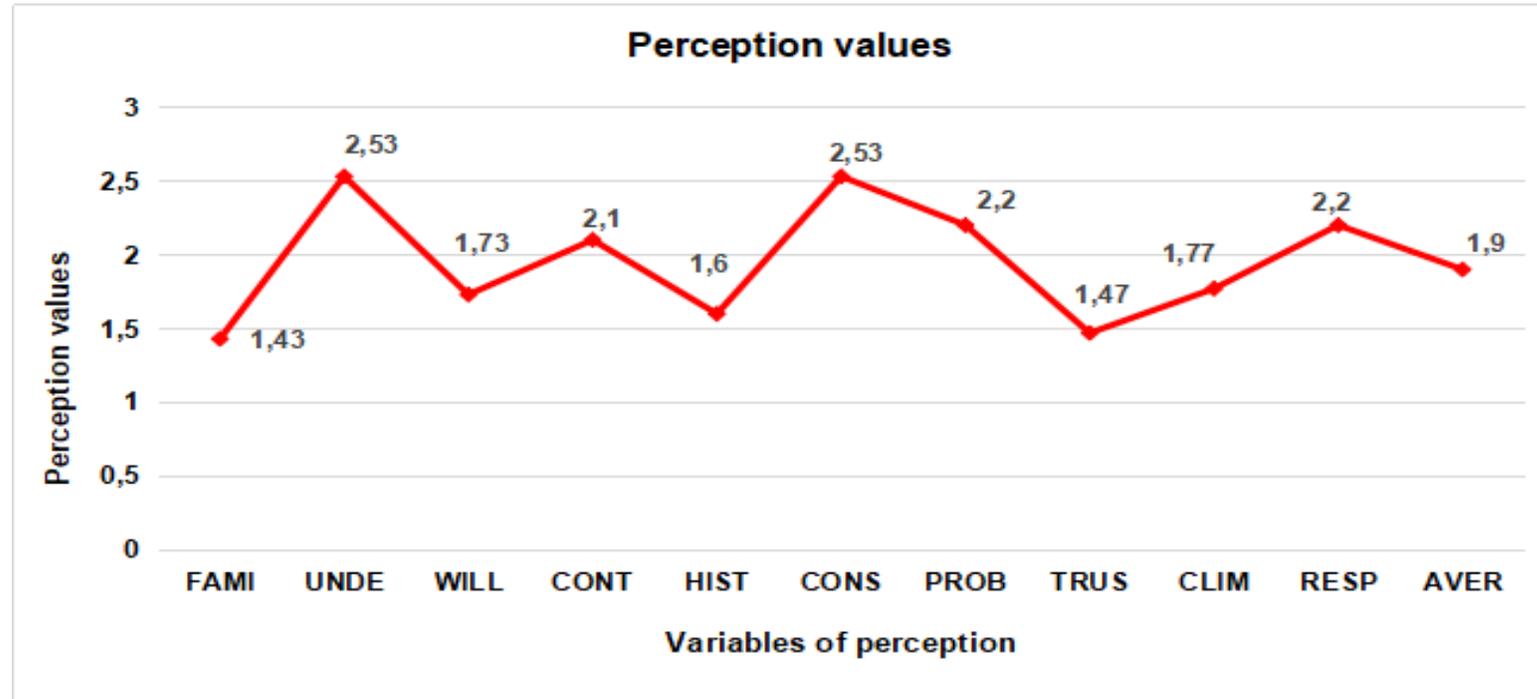


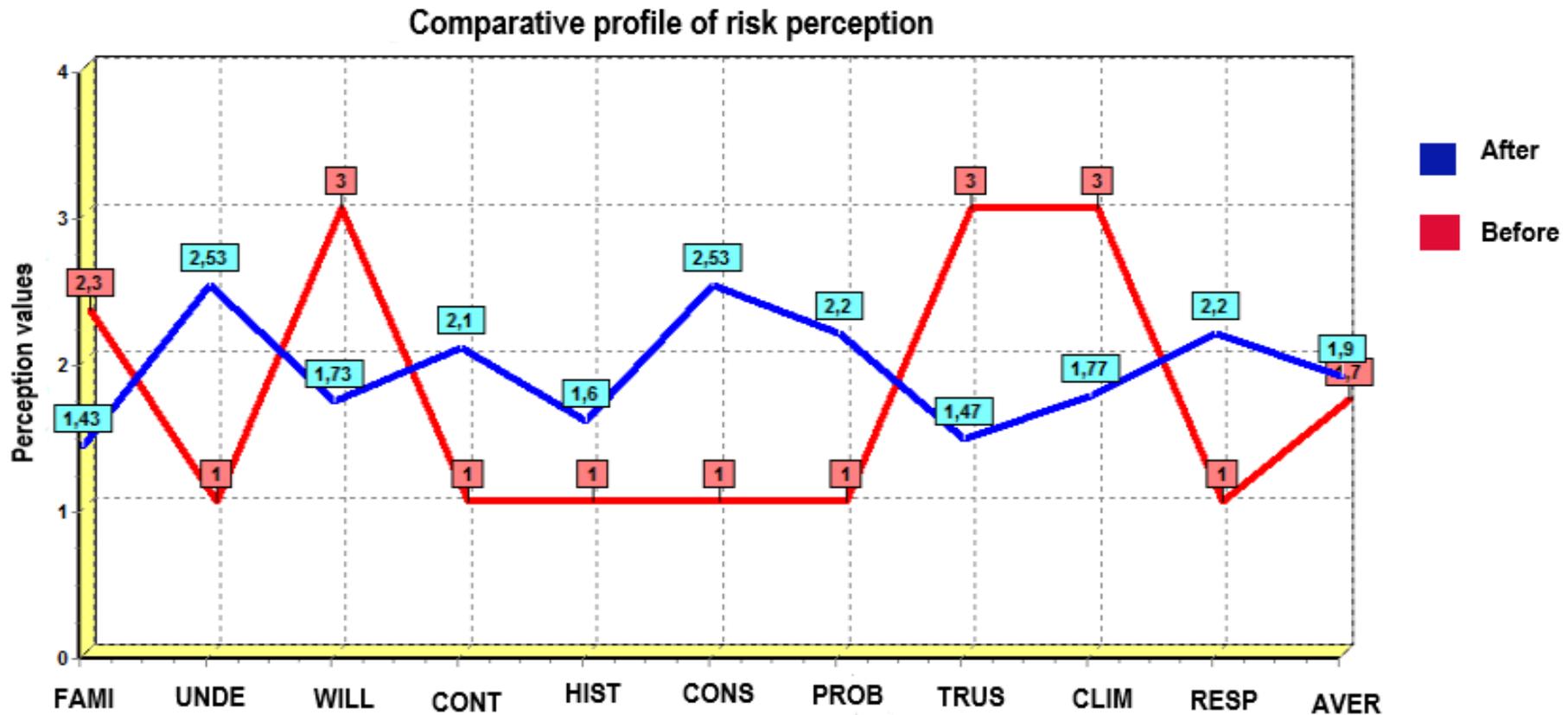
Figure 12. Matrix of the Culture of Biological Safety. CIRAH.

## Biological risk profile by perception variables once the technology is implemented. CIRAH



FAMI: Familiarity, UNDE: Understanding of risk, WILL: Willfulness, CONT: Controlability, HIST: Accident history, CONS: Immediate consequences, PROB: Estimate of the probabilities, TRUS: Trust in institutions, CLIM: Organizational climate, RESP: Response from supervisors. AVER: Average

Figure 13. Perception of biological risk by variable and average in CIRAH after the technology



FAMI: Familiarity, UNDE: Understanding of risk, WILL: Willfulness, CONT: Controlability, HIST: Accident history, CONS: Immediate consequences, PROB: Estimate of the probabilities, TRUS: Trust in institutions, CLIM: Organizational climate, RESP: Response from supervisors. AVER: Average

Figure 14. Perception of biological risk by variable and average in CIRAH before and after the technology

**Table 6. Comparison of two variables of biological risk perception**

<b>Variable</b>	<b>Relation</b>	<b>Before</b>	<b>Infante (2013)</b>	<b>Carbonell y Torres (2013)</b>	<b>After</b>
Familiarity (FAMI)	Indirect	CIBHO: 2,36 CIRAH: 2,3	2,08	1,86	CIBHO: 1,11 CIRAH: 1,43
Accident history (HIST)	Direct	CIBHO: 1 CIRAH: 1	1,03	2,27	CIBHO: 2,3 CIRAH: 1,6

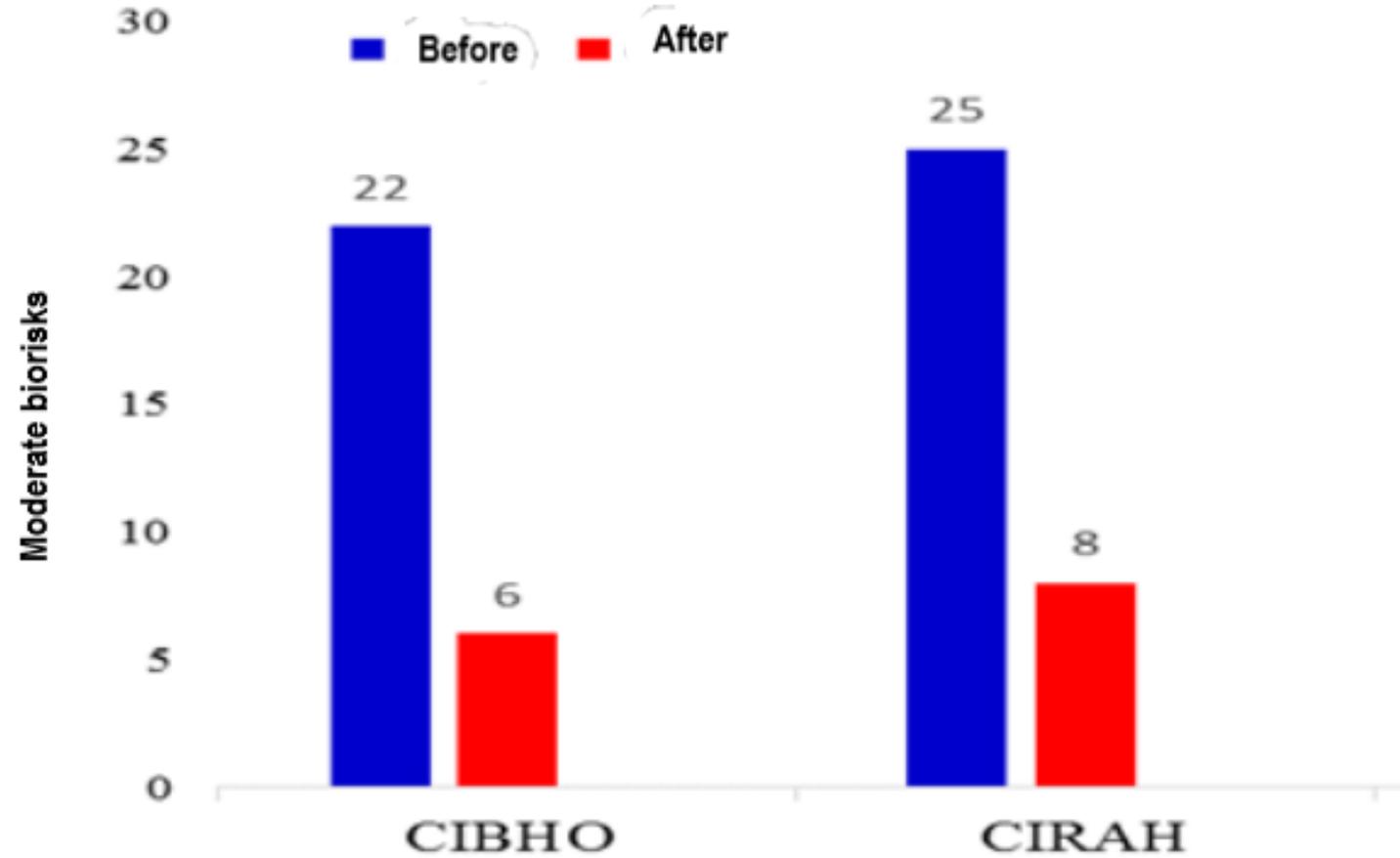


Figure 15. Moderate biorisks in CIBHO and CIRAH before and after the technology

## Specific causes



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## Conclusions

1. The technology conformed by a conceptual model of Biological Safety and its procedure with a process and risk based approach allowed the integration of Biosecurity into the processes of the organization to contribute to the reduction of biological risk, as well as to the prevention and promotion of health in the work scenario.
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## **Conclusions**

2. The selected indicators had a direct impact on the reduction of biological risk due to their action on changes in the behavior of personnel exposed to this type of risk and contribute to the prevention and promotion of health in the workplace.

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## **Conclusions**

3. The implementation of the technology in the CIBHO and the CIRAH made it possible to place Biological Safety on a higher plane, raise the quality of the products and services generated there and to prevent and promote health in the workplace.

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# Recommendations

Expand in the proposed technology the content referring to the Biosecurity as an element of the model to achieve a better protection of the worker, the community and the environment.

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PhD. Antonio Torres Valle

Centro de Immunología y Biopreparados  
Holguín, Cuba

[cibho@cibho.hlg.minag.cu](mailto:cibho@cibho.hlg.minag.cu)



***Current affiliation:***

Diagnostics Biochem Canada Inc.

London, Ontario

[dbc@dbc-labs.com](mailto:dbc@dbc-labs.com)



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# Publications

- ❑ Perception of biological risk in two science entities in the health sector in Holguín. Cuba. **Medicina y Seguridad del Trabajo** 2016; 62 (244).
  - ❑ Culture of Biological Safety as a basic tool for the design of biosecurity documents. **Revista Cubana de Higiene y Epidemiología** 2015; 53 (2).
  - ❑ Methodology implementation in order to evaluate the biological risks in the Centre for Research and Rehabilitation of Hereditary Ataxias of Cuba. A biosecurity surveillance method. **Medicina y Seguridad del Trabajo** 2014; 60 (237) 620-626.
  - ❑ General elements on zoonoses. **Correo Científico Médico** ISSN 1560-4381 CCM 2014; 18 (4).
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# Publications

- ❑ Biological safety in the health sector. Point of view. **Correo Científico Médico** ISSN 1560-4381 CCM 2013; 17 (2).
  - ❑ Biological risk management in the Center of Immunology and Biopreparados of Holguin (summary). **Correo Científico Médico** ISSN 1560-4381 2012; 16(3) Supl 1.
  - ❑ Basic aspects of the pathogenesis, immune response and Biosafety in the work with *Toxoplasma gondii*. **Correo científico médico**. CCM 2012 16 (1). ISSN 1560-4381.
  - ❑ Results of occupational safety and health integration and Biological Safety in the Quality Management System at CIBHO. **InFÁRMate** Año 7, Número 26. Mayo 2011. (inFÁRMate 2011; 7(26):e682-88).
  - ❑ Methodology for the evaluation of biological risk. **REVISTA ELECTRONICA “CIENCIAS HOLGUÍN”**, Vol. XV (4), Diciembre 2009.
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Licenciada Lily Massiel Sarro Acle, funcionaria encargada del Registro Facultativo de Obras Protegidas y de Actos y Contratos referidos al Derecho de Autor,

**CERTIFICO:**

Que la obra cuyos datos se consignan a continuación, aparece inscrita en el referido Registro con el número: **1241-04-2018**.

**Título:** Desarrollo de un modelo conceptual para la organización de la Seguridad Biológica en dos entidades de salud de Holguín.

**Tipo de Obra:** Literaria.

**Breve descripción de la obra:** La obra es una investigación que desarrolla un modelo conceptual para organizar la Seguridad Biológica con enfoque basado en sistema, proceso y riesgo. Se aplicó en dos entidades de salud de Holguín y se muestran los resultados obtenidos en las mismas que tributaron a la prevención y promoción de la salud en el ambiente laboral.

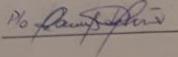
**Autoras:** Dailín Cobos Valdes;  
Mayra Ramos Lima.

**Titulares:** Centro de Inmunología y Biopreparados de Holguín;  
Centro para la Investigación y Rehabilitación de las Ataxias Hereditarias de Holguín.

**Dada en La Habana, a los 23 días del mes de abril de 2018.**

  
Funcionaria

  
SUBDIRECCIÓN  
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Para cualquier información

Calle 15 N° 604 e/ B y C, Plaza de la Revolución, CP10400, La Habana, Cuba.  
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