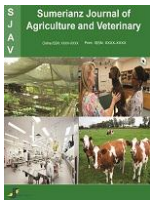
Sumerianz Journal of Agriculture and Veterinary, 2019, Vol. 2, No. 2, pp. 10-15
ISSN(e): 2617-3077, ISSN(p): 2617-3131
Website: https://www.sumerianz.com



Original Article Open Access

Biosafety in Research: Importance of Protecting the Environment and Health

Maria Lucia Moura*
Enfª Profª. Ms. Drª., University Santa Úrsula - USU Invited professor, PROMOLIFE - advice on worker's health – Teache, Brazil

Vanessa Guimarães
Enfª Profª Doctor Student., University Santa Úrsula - USU Invited professor, AHERJ – Nursing, Brazil

Abstract

The objective of this study was a brief review of published scientific papers on Biosafety in research and the importance of protecting the environment and health. Method: With the intention of defining the object of study and field of research for the reality that was intended to apprehend, productions were selected in the form of articles, testimonies, materials or booklets published in national and international periodicals, raising the subject on the Internet, books and journals linking Biosafety in post-signing research in May 2000, the debate period of the Cartagena Protocol, and its definitive conversion into the Biosafety Law in 2005, which currently regulates the use of biotechnology in the country. It was considered a time limit between 2000 and 2018/2019. Results: A total of 25 publications were identified among printed electronic journals, books and manuals. Four studies were discarded because they were not in the proposed scope. Only 21 studies were used. Conclusion: During the course of this research we can identify that Biosafety is part of the routine of laboratories of universities and health institutions with the intention of minimizing risks to the environment and health. The use of protective equipment becomes essential to avoid damages to health and the awareness of this use. Other important knowledge for workers is Regulatory Standards, NR6, and NR32.

Keywords: Biosafety; Risks; Biological.

1. Introduction

Brazil has had biosafety legislation since 1995, with the entry into force of Law 8.974/95, which established biosafety standards to regulate the manipulation and use of genetically modified organisms (GMOs) in the country. Ten years later, this law was replaced by a new one, Biosafety Law 11.105/05, which updated the terms of GMO regulation in Brazil, including research on containment, field experimentation, transport, import, production, storage and marketing Rech [1].

Still before Rech [1], before being sanctioned, this bill was submitted to the National Congress for two years under No. 2.401 / 03, and was widely discussed by all civil society, including scientists, members of non-governmental organizations (NGOs), the Federal Government and the Public Ministry, among others. Throughout this process, several public hearings took place, when the observations of all representations were heard.

The International Biosafety Protocol, also known as the Cartagena Protocol, was drafted in the late 1990s in the city of Cartagena, Colombia. After many negotiations, the Protocol was finally opened for signature in May 2000 during the 5th CBD meeting in Nairobi. After the debate period, in 2005, the project was definitively converted into the Biosafety Law, which currently regulates the use of biotechnology in the country. Because of all these steps and care, the Brazilian regulatory process is recognized internationally as one of the most rigid and complete in the world CPB [2].

In this context, today and in accordance with the Cartagena Protocol the Convention is the main international instrument to address biodiversity issues. It provides a comprehensive and holistic approach to the conservation of biological diversity, the sustainable use of resources and the fair and equitable sharing of the benefits derived from the use of genetic resources. Biosafety is one of the issues addressed by the Convention CPB [2].

This concept refers to the need to protect human health and the environment from the possible effects of modern biotechnology products and at the same time, biotechnology is recognized as a great potential for the promotion of human well-being, particularly in meeting the critical needs of food, agriculture and health.

2. Review

Biosafety comprises a set of actions designed to prevent, control, mitigate or eliminate risks inherent in activities that may interfere with or compromise quality of life, human health and the environment. (BRAZIL, 2010)

In this sense, Biosafety is treated by the Health Biosafety Commission (CBS) whose objective is to define strategies for action, evaluation and follow-up of actions related to Biosafety in order to have the best understanding between the Ministry of Health and related entities and entities BRAZIL [3].

*Corresponding Author

Thus, it is essential to consider care when dealing with high-risk biological agents - that is, highly transmissible and lethal, which depends on public health management, which is directly implicated in the health care and well-being of the population through risk prevention and mitigation of the effects of crises that originate in the interface between humans, animals and the environment.

The structure of the International Biosafety Protocol guides the use of the so-called Precautionary Principle, a fundamental principle of environmental law, which stipulates that if there are indications of the occurrence of risks to the environment and / or human health, steps are taken to avoid them, although there is no scientific evidence about its consequences or consequences Lisboa [4].

On the other hand, these concerns are part of the path of the construction of the field of scientific knowledge that today we infer to belong to Biosafety, whose focus is the search for control of the risks that work and the scientific and technological development can contribute to the nature and the life on the planet ROCHA, *et al.* [5].

Continuing this is a collaboration between the areas that directly or indirectly impact on health, optimizing resources and efforts respecting the autonomy of the various sectors. Public health is the science of improving and protecting health through the promotion of healthy life styles, researching the prevention of diseases and injuries, and the detection and control of infectious diseases.

This argument makes it clear that there is a concern to protect the health of entire populations, from a global level to regions, nations, communities, families and, ultimately, impacting individuals. Public health measures are mainly aimed at preventing disease and injury, not just the recognition, diagnosis and treatment of the disease.

On the other hand, a significant portion of public health work is aligned with health protection, particularly health measures that diminish the impact and increase resilience to important threats such as emerging infectious diseases and other risks to the population.

However, other non-health agencies, such as defense, emergency services and law enforcement, are also responsible for Biosafety especially in laboratories where high-risk biological agents are handled, researched, or stored.

In this way Biosafety is a term that encompasses the actions, systems and policies that protect human beings from exposure to harmful biological agents, it is necessary to adopt systems and adaptations with the advancement of technologies for research with high risk agents, and how it is knowledge of all requires the cooperation of a wide range of experts, such as scientists, policy makers, security engineers and law enforcement.

Based on this idea, the use of individual protection equipment, laboratory physical restraint systems and decontamination techniques are well known components of some Biosafety systems. It is very clear that there is a need to develop a national policy in security planning and among all relevant agencies and departments dealing with Biosafety issues [6].

It is worth emphasizing that there are still obstacles to the convincing and political will of decision makers of the benefits of Biosafety for public health and the national economy by granting such support even because it is known that in developing countries this system is not yet a priority in the [6].

In this sense, risk management, when recognizing the dangers of biological agents and planning strategies to reduce the risk to humans, the clinical process itself as there is a need for expert advice in the creation of technical protocols and appropriate procedures in the conduct of certain research logistic is another important area for the development of strategies to use the resources of the system and prompt response to possible events such as outbreaks and decisions, as we cannot forget the ethics involved in Biosafety as well. The importance of this reasoning reminds us that some institutions are already beginning to teach Biosafety principles at the undergraduate levels in the health area, as we know that there are specialization and refresher courses in Biosafety. In addition, there is a great effort to raise awareness among technologists and technicians in all sectors, this has definitely improved the level of Biosafety especially in hospitals and research laboratories.

Therefore, any work in the field of biological research requires immunization since this professional is exposed to preventable diseases and may infect other people and the environment must be free of contamination, as well as MAYER [7]. Involved to characterize the extent to which these individuals are considered protected for a particular job.

A stinging example of ignorance of Biosafety norms and the lack of preparation of public agencies to deal with the issue was the Césio-137 accident in September 1987 in Goiania, when a radiotherapy device abandoned in a disabled clinic was stolen and dismantled, exposing the population of that Capital to radioactive contamination BRAZIL [3].

In this context, we recall the advance of biotechnology combining biological disciplines such as genetics, molecular biology, biochemistry, embryology, cell biology, with technical disciplines such as chemical engineering, information technology and robotics, which requires the importance of Biosafety.

In fact, it becomes a significant point to believe that there should be a consensus among educators about the best practices to achieve Biosafety in laboratories and the variety of practices between different institutions, because the low incidence of associated infections when teaching in these environments suggests that these laboratories are relatively safe.

Another essential point in Biosafety is the use of personal protective equipment (PPE), established by NR 32, where it is recommended that all workers with possible exposure to biological agents should wear appropriate work clothes and in comfort conditions CAMISASSA [8].

We can see that a reporting system should be structured as a database, including not only incidents but also reports of near misses, defined as situations that demanded a response, but since there were no infections or major consequences, it was not given much importance.

In view of this statement it is known that these small incidents can be the result of a series of common errors or failures. Is it known that some institutions have expressed reluctance to share information about Biosafety incidents due to the fear of how this information can be shared by other organizations and end up out of control and nobody wants to be penalized is not it? Therefore, redoubling attention and making use of protective equipment is strictly necessary in these environments.

On the other hand we can analyze a biological risk by studying the process that evaluates multiple factors to determine the risk to laboratory workers, the community or the environment of working with an infectious agent, toxin or other biological risk. Biological risk assessment is used to determine the appropriate level of Biosafety for each project conducted within a laboratory Emmert [9].

Research with biological agents becomes a major hazard, but it is important for the prevention and diagnosis of diseases. Therefore, working with recombinant deoxyribonucleic acid (*rDNA*), toxins, animals and cells, can be a source of infection with highly infectious pathogens, should be well managed.

Steenhuysen [10] and National Institute of Health (NIH) [11] point to important questions such as the risks of working with biological agents as they are real risks and there is evidence due to the death of an infection researcher with an attenuated strain of *Yersinia pestis* in Chicago in September 2009, as well as cases of laboratory-acquired vaccinia infection, as well as additional percutaneous examination on exposure in the United States between 2005 and 2007.

The CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC) [12] also reported that three laboratory scientists were infected by *Francisella tularensis*, a wild-type contaminant strain samples from a tularemia vaccine strain.

It is worth remembering that the Regulatory Norms (NR) are Occupational Safety Measures determined by the Ministry of Labor and Employment (MTE) that aim to ensure safety and occupational medicine in the workplace. The teams involved directly and indirectly must be trained Everyone needs to know their duties very well, and everything that needs to be done in case of work accidents. This applies not only to the Safety Team Manager, but also to all operators and technicians Barsano and Barbosa [13].

Biological containment is the second cornerstone of biosafety, which includes the inclusion of agents as much as possible during handling and transport [14, 15].

Notwithstanding, team members are responsible for their own health and safety and must take reasonable care to avoid adversely affecting the health or safety of any other person by any act or omission. Infectious diseases can be transmitted by "puncturing", the collective term used for infected needles or other cutting tools that cause injury, so the importance of understanding the regulatory standard NR32 Araujo [16].

Thinking in this way prevention is the most effective approach to managing biological risks. Future workers / researchers should be educated about the biological risks that can be occupationally exposed, the types of exposures that put their health at risk, the nature and significance of such risks, as well as first aid, help and follow-up for possible exposures. This information should be strengthened annually at any time of any significant change in work responsibility, and recognized and suspect exposures.

The importance of this rationale is that scientists throughout the world work daily in laboratories to find cures for diseases, improve human, animal and plant health, and better understand infectious agents and toxins.

We understand that in all professions, laboratory workers face specific risks in their daily work, which can vary greatly from project to project. Researchers apply the principles of Biosafety and follow them carefully to ensure the safety of people inside and outside the laboratory including the environment.

To continue, there are inspection checklists that help ensure that a facility meets the physical, biological, and managerial requirements for a given level of biosafety. These lists facilitate approval by the Institutional Biosafety Committee (IBC), providing design and internal monitoring serving as compliance documentation.

According to Dann and Irwina [17] inspection and verification list:

- ✓ Who are responsible and how can they be contacted?
- ✓ What is the nature of the experience and how is it identified?
- ✓ What is the prescribed level of containment? Do physical facilities meet this level?
- ✓ What are the specific physical and biological measures used for containment?
- ✓ Are the Standard Permit Conditions, Supplemental Conditions (SOPs) available and followed?
- ✓ Is there any evidence of impairment in relation to containment?
- ✓ How is the area guaranteed? What security is required?
- ✓ Is there a written plan to respond to the loss of restraint?
- ✓ What is the most likely cause of a violated containment?
- ✓ How are materials discarded at the end of the experiment?

In Brazil, there are two aspects of biosafety: legal and practiced. The first deals with the manipulation of genetically modified organisms (GMOs) and stem cells, regulated by Law 11.105/05. The second is related to the chemical, physical, biological, ergonomic and accident risks found in work environments, supported mainly by the regulations of the Ministry of Labor and Employment (MTE), Resolutions of the National Health Surveillance Agency (ANVISA) and National Council for the Environment (CONAMA), among others [18].

Table-1. Classification of the main occupational risks in groups according to their nature and the corresponding color standardization

GRUPO 1: VERDE	GRUPO 2: VERMELHO	GRUPO 3: MARROM	GRUPO 4: AMARELO	GRUPO 5: AZUL
RISCOS FÍSICOS	RISCOS QUÍMICOS	RISCOS BIOLÓGICOS	RISCOS ERGONÔMICOS	RISCOS ACIDENTES
Ruídos	Poeiras	Vírus	Esforço físico intenso	Arranjo físico inadequado
Vibrações	Fumos	Bactéria	Exigência de postura inadequada (local de trabalho inadequado)	Piso escorregadio
Radiações ionizantes (raio x, alfa gama)	Névoas	Protozoários	Levantamento e transporte manual de peso	Máquinas e equipamentos sem proteção
Temperaturas extremas:	Neblinas	Fungos	Postura inadequada	Ferramentas inadequadas ou defeituosas
Frio	Gases	Parasitas	Controle rígido de produtividade	Iluminação inadequada
Calor	Vapores	Bacilos	Imposição de ritmos excessivos	Eletricidade
Pressões anormais	Substâncias, compostos ou produtos químicos em geral	Sangue	Trabalho em turno e noturno	Probabilidade de incêndio ou explosão
Umidade			Jornada de trabalho prolongadas	Armazenamento inadequado
			Monotonia e repetitividade	Animais peçonhentos: (mordida de cobra, aranha, picada de escorpião, barbeiro etc)
			Outras situações causadoras de stress físico/ou psíquico	Outras situações de risco que poderão contribuir para a ocorrência de acidentes

[13]

Therefore, the determination of levels of containment should be prioritized in universities' laboratories, since with the emergence of new technologies, operational procedures for the manipulation of pathogenic biological agents should be adequate to guarantee the safety of professionals, academics and the environment Sangioni, *et al.* [19].

Knowing the equipment of Individual Protection (EPI, s) should provide the record of approval of the MTE. (NR6 Ordinance SIT nº194, of December 7, 2010). In order for the containment to perform its function within the laboratory, knowledge about the handling of personal protective equipment (PPE) and its availability for its use is essential. Such protective equipment are primary barriers that protect the physical integrity and health of the professional as the environment in which it operates [20].

Continuing the collective protection equipment (EPC, s), have the function of protecting the environment and the health of the laboratory workers in addition to their integrity. They are biological safety booths, chemical exhaust hoods, fire extinguishers, emergency shower and eyewash [20].

3. Myths

- Are PPE's uncomfortable? PPE's were really very unreliable in the past, but there are now EPI's made from lightweight and comfortable materials. The feeling of discomfort is associated with factors such as lack of training and misuse. The worker refuses to use PPE only when he has not been aware of the risk and the importance of protecting his health. This recognition contributes to non-resistance to use [20].
- Are PPE's expensive? studies show that spending on such equipment represents, on average, less than 0.05% of the investments required (in some cases, the cost drops below 0.01). On the other hand, the non-use of PPE and non-compliance with legislation may result in fines and labor actions, which is becoming much more costly for the employer [20].

3.1. Caution: Worn Protective Clothing Must Be Torn To Prevent Reuse [20]

The Ministry of Health recommends that the biohazard symbol be placed at the entrance of the laboratory, also informing the manipulated microorganism, the risk class, the name of the researcher responsible, the address and the contact telephone number. In addition, it should contain the phrase: "No entry for unauthorized persons".

In this way, it can be considered that the basic foundation of biosafety is to ensure the expansion of scientific knowledge, aiming at the development of technologies and the advancement of technological processes. This set of actions should be based on the specific principles of the activities for which they were designed, in order to focus on protecting human, animal and environmental health. In this context, the worker deserves to be highlighted, since the main objective of biosafety is the minimization of risks, which depends directly on the field of action, which inserts it in several contexts, which reflect the diversity of biosafety fields [21].

4. Results and Discussion

A total of 25 publications were identified among printed electronic journals, books and manuals. Four studies were discarded because they were not in the proposed scope. Only 21 studies were used. 8 manuals on Biosafety were found. We also found 3 books on safety in research. We found 1 doctoral thesis transformed into an article, 7 articles on the subject were used all online. We also find 1 primer and the Cartagena Protocol itself. We also find a PDF book of the Discipline Biosafety EAD. In relation to the time limit, the publications follow: In the year 2000 was found 1 publication. In 2002, 2005 and 2007 only one publication each. In the year 2008, three publications were found. In 2009 we found two publications. In the year 2010 we found a publication. And in 2012, two publications. In 2017 a publication. In the years of 2013, 2014, 2016 and 2018, we find two publications each.

4.1. The Following Table Contains the Detailed Studies

Table-2. Studies used in research

Study Name	Author (es)	Year of publication
Cartagena protocol on biosafety to the convention on biological diversity	Secretarial of the convention on Biological Diversity	2000
In pursuit of a foreign policy of the Brazilian environment: three examples and an exception to the rule	Lisbon VM	2002
Knowledge construction in health: study on biosafety teaching courses in the area of health	Coast MAF	2005
Biosafety in Microbiological and Biomedical Laboratories	Wilson DE, Chosewood LC	2007
Evidence- based biosafety	Kimman TG, Smit E, Klein MR	2008
Pratical Guide To Containment	Dann A, Irwina R	2008
Laboratory-acquired vaccinia CDC		2008
Plague researcher in Chicago dies from infection	Steenhuysen J	2009
Guidelines for Research Involving Recombinant Dna Molecules	NIH	2009
Biosafety in Health	Brazil	2010
Biosafety, Protection Environmental and Health	Rocha SS, Bessa BCT, Almeida PMA	2012
Biosafety Subjecto EAD	Nunes PF	2012
Principles of Biosafety applied to teaching laboratories University of Microbiology and Parasitology	Sangioni AL, Pereira BID, Vogel FSF Botton AS	2013
Biosafety Guidelines for Handing Microorganisms in the Teaching Laboratory	Emmert E	2013
Occupational Health and Safety	Barsano PR, Barbosa RP	2014
Immunology cells Interactions cell cell in answers immune specific	Mayer G	2014
Biosafety and good Practices Laboratory	Keys FJM	2016
Information Council on Biotechnology When and how it was created the Brazilian Biosafety Low l	Rech E	2016
Regulatory Standads Nrs 6 e Nr 32	Araújo MG	2017
Safet and Health at Work	Camisassa QM	2018
Research Biosafety	Moura MLC	2018

5. Conclusion

During the course of this research we can identify that Biosafety is part of the routine of laboratories of universities and health institutions in order to minimize risks to the environment and health. The use of protective equipment becomes essential to avoid damages to health and the awareness of this use. Other important knowledge for workers is Regulatory Standards, NR6, and NR32.

Ensure containment areas, know the checklists, know the occupational hazards and their corresponding colors. The teaching of the discipline Biosafety in undergraduate studies strengthens the constant concern, because in this way prevention is the most effective approach to biological, physical and chemical risks management. In this perspective it is not intended to exhaust the subject. We found many manuals and booklets. Publications on Biosafety as a whole are believed to be necessary.

References

[1] Rech, E., 2016. "Information council on biotechnology. When and how the biosafety law in Brazil." Available: https://cib.org.br/faq/when-and-as-to-go-create-a-lei-de-biosafety-in-brazil/

[2] CPB, 2000. "Cartagena protocol on biosafety to the convention on biological diversity. Secretariat of the convention on biological diversity." Available: https://www.cbd.int/doc/legal/cartagena-protocol-en.pdf

[3] BRAZIL, 2010. *Ministry of health. Health biosafety: Priorities and action strategies*. 4th edition ed.

[4] Lisboa, V. M., 2002. "In search of an external brazilian environmental policy: Three examples and one exception to the rule." *Rev São Paulo in perspective*, vol. 16, pp. 44-52. Available: http://www.scielo.br/pdf/spp/v16n2/12110.pdf

[5] ROCHA, S. S., BESSA, B. C. T., ALMEIDA, P. M. A., and Biosafety, 2012. "Environmental Protection and Health: composing the mosaic." *Rev. Science & Collective Health*, vol. 17, pp. 287-292. Available: http://www.scielo.br/pdf/csc/v17n2/a02v17n2.pdf

[6] Moura, M. L. C. A. "Biosafety in research." Available: https://www.enfernew.com.br/2018/08/a-biosafety-nas-surveys.html

[7] MAYER, G., 2014. *Immunology. Cell mediated immunity: Cell-cell interactions in immune-specific responses. Translation*. 5th ed ed. USA: Myres Hopkins.

[8] CAMISASSA, Q., 2018. *Safety and health o work. Method*. 4th ed. Rio de Janeiro.

[9] Emmert, E., 2013. "Biosafety guidelines for handling microorganisms in the teaching laboratory: Development and rationale. USA." *Journal of Microbiology and Biology Education*, vol. 14, pp. 78–83.

[10] Steenhuysen, J., 2009. "Plague researcher in chicago dies from infection." *Reuters Health Clin Infect Dis.*, vol. 49, Available: https://www.reuters.com/article/us-plague-death/plague-researcher-in-chicago-dies-from-infection-idUSTRE58K3J120090921

[11] National Institute of Health (NIH), 2009. "Guidelines for research involving recombinant DNA molecules.Washington, dc: Us department of health and human services, national institutes of health. Us department of health and human services." Available: http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html

[12] CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC), 2008. "Laboratory-acquired vaccinia." *MMWR Morb Mortal Wkly Rep.*, vol. 57, pp. 401-404.

[13] Barsano, P. R. and Barbosa, R. P., 2014. *Hygiene and safety at work*. São Paulo: Editora Érica.

[14] Kimman, T. G., Smit, E., and Klein, M. R., 2008. "Evidence-based biosafety." *Clin Microbiol Rev.*, vol. 21, pp. 403-425. Available: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2493080/pdf/0014-08.pdf

[15] Wilson, D. E. and Chosewood, L. C., 2007. *US Department of Health and Human Services; Centers for Disease Control and Prevention; National Institutes of Health. Biosafety in Microbiological and Biomedical Laboratories*. Washington, DC: US Government Printing Office.

[16] Araujo, M. G., 2017. *Revised regulatory norms. Safety and occupational health legislation*. 3rd Ed ed. GVC Publishing House.

[17] Dann, A. and Irwina, R., 2008. "Pratical guide to containment." Available: https://vtechworks.lib.vt.edu/bitstream/handle/10919/78423/ISBPracticalGuidePlantContain.pdf?sequence=1&isAllowed=y

[18] COSTA MAF, 2005. "Construction of knowledge in health: a study on the teaching of biosafety in middle level courses in the health area of the Oswaldo Cruz Foundation. 154f." Available: https://www.arca.fiocruz.br/handle/icict/19555

[19] Sangioni, A. L., Pereira, B. I. D., Vogel, F. S. F., and Botton, A. S., 2013. "Principles of biosafety applied to laboratories of university teaching of microbiology and parasitology." *Rev Science Rural*, vol. 43, Available: http://www.scielo.br/pdf/cr/v43n1/a0313cr4897.pdf

[20] Chaves FJM, 2016. "Manual of biosafety and good laboratory practices." Available: http://www.biot.fm.usp.br/pdf/Manual_de_biosseguranca_e_Boas_Praticas_Laboratoriais_LAB_DE_GENETICA_CARD_MOLECULAR_INCOR.pdf

[21] NUNES, P. F., 2012. "Biosecurity: Discipline. Ead.Unesp." Available: http://subjects.nucleoead.com.br/pdf/Biosafety.pdf