RECIIS
Revista Eletrônica de Comunicação Informação & Inovação em Saúde
[www.reciis.icict.fiocruz.br]
ISSN 1981-6278

Essays

The role of the Internal Biosafety Committee: the experience of the Oswaldo Cruz Institute

DOI: 10.3395/reciis.v3i4.235en

Maria Eveline de Castro Pereira
Internal Biosafety Committee, Oswaldo Cruz Institute-Fiocruz, Rio de Janeiro, Brazil
maria@ioc.fiocruz.br

Cíntia Moraes Borba
Internal Biosafety Committee and Laboratory of Taxonomy, Biochemistry and Bioprospection of Fungi, Oswaldo Cruz Institute-Fiocruz, Rio de Janeiro, Brazil
cborba@ioc.fiocruz.br

Claudia Jurberg
Oswaldo Cruz Institute - Fiocruz and Institute of Medical Biochemistry, UFRJ - Coordination of the Oncobiology Program Dissemination Unit, UFRJ, Rio de Janeiro, Brazil
cjurberg@bioqmed.ufrj.br

Abstract
This paper describes the creation and restructuring of the Internal Biosafety Committee of the Oswaldo Cruz Institute (CIBio / IOC), as well as the experience acquired during the implementation of a biosafety management system, giving special attention to the model chosen based on a Network of Commitment. It also highlights the three macro-foci defined by the Committee as being fundamental and ongoing projects of the Institution - renovating laboratory infrastructure, purchasing protective equipment, and professional capacity building - with the intention of establishing and maintaining high-quality work in the laboratory environment.

Keywords
internal biosafety committee; biosafety management; genetically modified organism; biosafety legislation

Introduction

Applied Genetic Engineering emerged in 1973 in California, United States, with the transfer and expression of the insulin gene to Escherichia coli, which caused a strong reaction in the global scientific community, and led to the Asilomar Conference (BOREN & SANTOS, 2004). During the meeting, held in 1976, a large number of scientists decided to suspend certain types of laboratory experiments, as S. Cohen and H. Boyer's experiments presented a genuine possibility of authentic genetic manipulation (MOSER, 2004). It was necessary to establish mechanisms to ensure that the techniques could be used without risk to humankind and the environment. Therefore, a number of biosafety rules and regulations to be used with these technologies were published and implemented.

In Brazil as in many Latin American countries specific laws set forth biosafety rules to regulate the use of recombinant technology and the release of genetically modified organisms (GMOs) into the environment. The Brazilian biosafety legislation - Law No. 11.105/05, 24/03/2005 (BRAZIL, 2005), which repealed Law No. 8. 974 of 05/01/1995 provides for safety guidelines and monitoring mechanisms for activities involving GMOs and their byproducts, in addition to regulating items II, IV and V of paragraph 1 of Article 225 of the Federal Constitution, which addresses environmental protection:

> *Everyone has the right to an ecologically balanced environment, an asset of common use and essential to a healthy life. The Government and the community have the duty to defend it and preserve it for present and future generations. To ensure the effectiveness of this right, the Government must: [...]preserve the diversity and integrity of the genetic heritage of the nation, and monitor institutions dedicated to genetic material research and manipulation; [...]require a previous assessment of the environmental impact whenever a work or activity is to be deployed that may cause significant environmental degradation; such works or activity shall be disseminated in the media; [...]control the production, sale and use of techniques, methods and substances that represent a risk to life, to the quality of life and the environment (BRAZIL, 1988).*

In this context, the political model adopted by Brazil as a mechanism for decision making concerning the commercial release of GMOs is a centralizing agency, like the European model, where central competent institutions require proof of food and environmental safety before approving each GMO (VARELA, 2005).

When the Biosafety Law (Law 8974) was enacted in the country in 1995, it was considered appropriate and praised by various sectors of society. However, ten years later a hectic period emerged, when it was replaced by Law 11.105/05, which was also considered a breakthrough in legal terms, as it was in tune with the Rio Declaration 2 , with the Convention on Biological Diversity , and with the Cartagena Protocol . It provides for safety guidelines and mechanisms for monitoring activities involving GMOs and their byproducts, and aims at the protection of human, animal and plant health and the compliance with the precautionary principle for environmental protection (NODARI, 2007). Additionally, it establishes the National Biosafety Council (CNBS), restructures the National Technical Committee on Biosafety (CTNBio), provides for the National Biosafety Policy (PNB), establishing that the creation of the Internal Biosafety Committee (CIBio) would be mandatory in all entities (whether public or private) dedicated to education, scientific research, technological development and industrial production through the use of techniques and methods of genetic engineering or carrying out research with GMOs.

The law sets forth that a CIBio should be comprised of trustworthy individuals, with proven scientific knowledge and experience to evaluate and monitor the work with GMOs and their byproducts developed in an institution, in addition to the possibility of participation of one member from outside the scientific community. The powers of CIBio expanded with the publication of Law No. 11.105/05, and started to encompass the following aspects:

- Accreditation: assessing and reviewing all proposed activities involving GMO / genetically modified animals (GMA) and identifying risk factors and situations, checking the qualification and background of the personnel involved, approving projects involving GMOs that offer no risk to humans and animals, and submitting pleas and documents to CTNBio regarding GMOs that pose a higher risk. In addition to authorizing the nationwide transfer of GMOs.

- Monitoring: maintaining individual progress reports for each activity or project, and executing at least one annual inspection of the accredited facilities, in order to ensure compliance with the requirements and necessary levels of biosafety.

• Information: developing and disseminating standards concerning the institution, in compliance with the Brazilian laws; keeping workers and members of the community informed when they are subject to risk arising from activities involving GMOs and establishing a biosafety training program.

• Accident: establishing procedures, and notifying CTNBio and relevant recording and monitoring institutions and agencies of accidents or incidents occurring during the research and projects in the area of genetic engineering, and sending reports to competent authorities within up to five days.

CIBio must assess whether the actions performed within the institutional framework comply with the law. Varella (2005) warns that, when there is lack of compliance all efforts must be made to ensure that irregularities are fixed, under the risk of being liable for omission in the face of public authorities.

The experience of the Oswaldo Cruz Foundation

The background of the Oswaldo Cruz Foundation (Fiocruz) is based on its commitment to public health and the application of environmental sanitation policies, and community vaccination against pathogenic micro-organisms. At first, the researchers' work was characterized by heroic acts: convinced of the beneficial nature of their findings, many were the first to be vaccinated. With the passage of time, awareness of biological hazards started to increase, leading to the elaboration of manuals, staff training, and the creation of protocols and regulations (CTBIO, 1997).

The Technical Biosafety Committee of the Oswaldo Cruz Foundation (CTBio / Fiocruz) was established on April 24, 1995, out of the enthusiasm of a group of 21 professionals with heterogeneous backgrounds in the Social and Biological areas. Those professionals were the creators – along with technicians from the Brazilian Company for Agricultural Research (Embrapa) – of a proposition for a replacement of the biosafety bill that addressed the management of GMOs, which resulted in Law n° 8. 974/95. Nevertheless, the legal aspect was not the focus of the Committee. Being established under the Vice Presidency of Technological Production and Development, it attempted to ensure that research, teaching, technology development and production activities and the provision of service involving risk agents complied with safety, quality and ethics standards.

Following that, the Committee for Risk Identification and Prevention and the Technical Biosafety Committee were established within the sphere of the CTBio / Fiocruz. Their areas of expertise were non-GM pathogens and their products. It was only in November 1996 that the Internal Biosafety Committee of Fiocruz was established. Its purpose was to organize the documentation needed to request the Certificate of Quality in Biosafety (CQB) for all laboratories of the institution that used recombinant technology in their research. This certificate is the authorization granted by CTNBio to institutions that allows them to carry out projects and activities involving GMOs and their byproducts. Following the guidelines of CTNBio, the accreditation process for projects involving the manipulation of GMOs was decentralized, under the claim that Fiocruz was an institution with 15 technical-scientific units, and some of them were located in other Brazilian states. Therefore, it would be difficult for a single committee to monitor all activities involving GMOs. Thus, those manipulating GMOs at the time created their Internal Biosafety Committee (CIBio), as required by law. Units of Fiocruz whose work did not involve the manipulation of GMOs, aware of discussions about safety concerning risk agents and of the Biosafety Law, established the Biosafety Committees (CBio). The presidents of CIBio and CBio participate in CTBI / Fiocruz, without a relationship of direct subordination.

The first CIBio of the Oswaldo Cruz Institute (IOC) was established by the Presidency of Fiocruz on 12/08/1998, with four members and a chairman Dr. Hermann Gonçalves Schatzmayr. The task of reviewing the projects that had already been registered in 1996 began, as well as the registration of new groups applying for accreditation from CTNBio.

Restructuring of the Internal Biosafety Committee of the IOC

In November 2002, CIBio / IOC was completely restructured and expanded to provide consultancy and establish norms, under the directorate, with the role of providing guidance on the prevention and minimization of risks inherent to the activities developed in the laboratories of the Institute, that is, regardless of whether such activities involved GMOs or not.

The Committee - which was previously small due to the lack of basic infrastructure, consisting of four scientists and an architect who met occasionally – increased in size and included 11 members. Additionally, an Executive

Secretariat was established with full-time exclusive team, including an administrator and an expert in labor safety engineering with a background in architecture. It is currently located on the second floor of the Gomes de Faria Pavilion, in the Fiocruz campus, Rio de Janeiro, with two well-equipped rooms capable of accommodating meetings and the Institute's researchers or CTNBio representatives.

With facilities suitable for their operation, CIBio / IOC began to tackle its major challenge - to undertake a biosafety project whose core aspect was the behavioral change of the staff of the Institute. It was clear that biosafety project of a biomedical research institution in all its stages - diagnosis, design, implementation and evaluation - requires an increasing level of expertise, depending on the risks and complexities of its activities. It is not just a theoretical or abstract knowledge, though, but one that is applied to the regular activities of organizations, promoting decision-making abilities and the triggering of actions (TEIXEIRA FILHO, 2000).

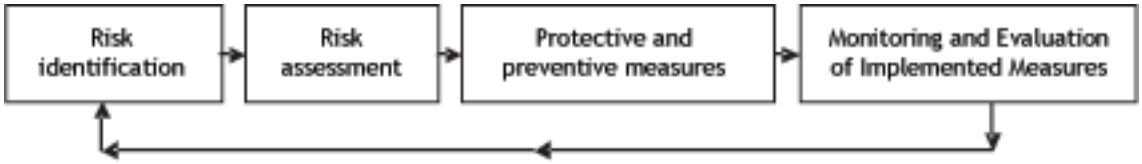
CIBio / IOC initially sought to expand the competencies of new Committee members, encouraging them to participate in events, congresses, and courses. It concurrently held research meetings and discussions on the legislation in force that enabled the preparation of the "Handbook on Procedures concerning the Manipulation of Genetically Modified Organisms and Animals", establishing the duties of the chairman, members and executive secretariat; defining the responsibilities of researchers and chiefs of laboratory, as well as giving instructions and providing forms to request CQB. In the wake of these activities, a new registration of projects involving GMOs was done, with laboratory inspection, and submitting the activities report for approval by CTNBio (CIBio / IOC, 2002).

Biosafety Management

According to Cardella (2008), managing means coordinating efforts to achieve the proposed goals. From the standpoint of CIBio, biosafety management is a set of principles, strategies, guidelines and procedures designed to minimize risks that could endanger the health of humans, animals, the environment, and the quality of the work being carried out. This concept also includes the identification, assessment, containment and monitoring measures, as shown in Figure 1. With a detailed survey of agents manipulated, routines undertaken, and available technology and infrastructure, it is possible to assess the level of containment that will define specific biosafety actions to be adopted by each institution, and which must be combined with a continuous education plan based on local and international standards.

The management model adopted by CIBio / IOC is based on a Network of Commitment comprised of (a) Working Groups (GT) – professionals working at the Committee with different backgrounds - and (b) representatives of the IOC Laboratories, playing the role of mediators, presenting the problems found in their laboratories, collaborating in data surveys and especially in decision-making processes. This work method allows biosafety projects prepared by CIBio / IOC to be prioritized and developed along with the community, thus minimizing conflicts.

The GT coordinators are empowered to make up their teams, hold meetings and collect



Source: COSTA (2000)

Figure 1 – Risk management.

information for the preparation of projects. This usually occurs in accordance with the workflow shown in Figure 2. Once a problem needing intervention is identified, the GT responsible for that area runs a diagnosis through the mediators and / or performs inspections, studies the available legislation on the subject, and checks how the other local and international institutions deal with that situation. If necessary, where the case involves the acquisition of new products, samples for evaluation are requested from vendors, or members of the Work Group may even visit their facilities to learn details about the manufacturing process.

During the elaboration of a project, the components proposed by Costa (2000) are taken into account, whenever possible: occupational

aspects (determined by the safety conditions of the laboratory); educational aspects (examined from a point of view of placing importance on human resources, and consequently with the aggregation of ethical, philosophical and technical principles); social aspects (determined by actions for the optimization humanization and of the work processes); informational aspects (inserted in the communication process being practiced by the institution); normative aspects (a set of regulating actions needed for the development of laboratory activities); organizational aspects (as a reflection of organizational culture and climate); and lastly the technological aspects, due to the constant evolution of science, with the introduction of new equipment, techniques, etc. It is with these premises that CIBio / IOC acts in its projects, aiming at meeting not only the requirements of legal biosafety, currently regulated by Law No. 11. 105/05, but also the biosafety in practice, whose origin is directly related to the social and occupational protection of workers (Costa, 2005).

After completion, the project undergoes two approval processes: the first one is internal, when it is presented by the GT to other members of the Committee, and the second is external, when

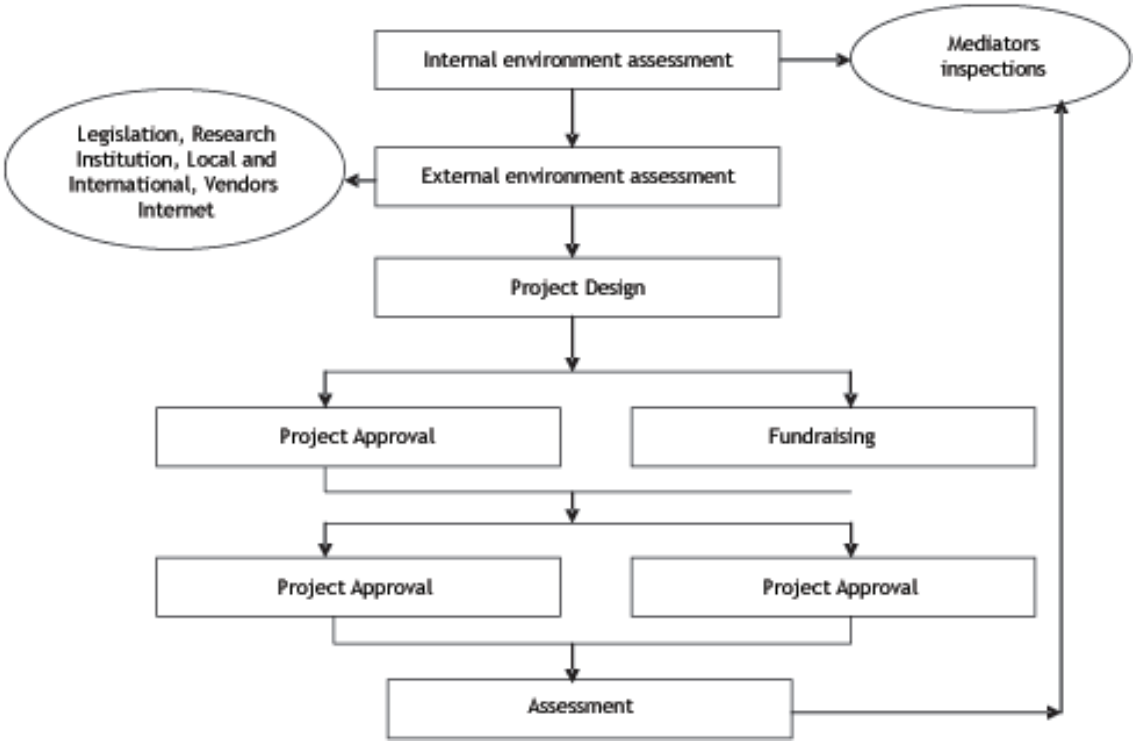


Figure 2 – Projects´ elaboration by the CIBio / IOC Work Groups.

it is brought to the IOC directorate. Financing can be acquired through treasury resources or through incentive agencies. The implementation of the project depends on the work schedule defined in the institutional sphere, or by the funding agencies. Once the project is approved, all steps are monitored. Monitoring aims at intervening in situations unforeseen by pre-planning activities. One final step remains to be executed after the project is completed: evaluation. It is at this point that CIBio / IOC assesses whether the goals have been achieved, as well as the opinion of the end user, through a system known as feedback (IBIAPINA, 2005).

With the purpose of strengthening the management of biosafety adopted at the IOC, CIBio / IOC works along with the Coordination of Information, Communication and IT (ICI), which is responsible for the unit's entire internal communication. Seeking to transform the organization by implementing a culture of prevention, all efforts are aligned towards the dissemination of clear and direct data that can really be applied towards biosafety training, using the IOC Report as a strategy – a weekly journal for internal communication – in order to disseminate standard procedures, new projects,

events (workshops and seminars), and new partnerships entered into by the Committee. This partnership in communication has a direct impact on organizational culture, encouraging Institute researchers, students and service providers to join the discussion focused on a Committee project – information on biosafety –in a continuous process of professional capacity building.

Managing the flow of information is an indispensable element to understand the processes in a given institution (ARAÚJO JUNIOR & ALVARES, 2007). It can contribute towards greater acceptance by those involved in the construction of a healthy and safe environment. In this context, the IOC report is undoubtedly a vehicle for the systematic dissemination of information, thus taking on a strategic role in the process of communicating and monitoring information. Marchiori (2006) believes that communication has become extremely important in companies concerned about the information flow, thus starting a dialogue with their several interest groups, and thus creating a change in attitude.

Projects run by CIBio/IOC

Of all the projects designed and implemented by CIBio / IOC over the past years (2002-2008), three macro-foci were defined by the Committee as being key and continuous projects in the institution:

(a) renovating laboratory infrastructure in order to meet the biosafety levels required, with the adoption of risk-containment measures: prioritization of laboratories manipulating GMOs, laboratories attempting to qualify as National and / or Regional Reference Laboratory for the National Networks of Epidemiologic and Environmental Surveillance in Health (Ordinance SVS/MS/070, 12/23/2004) of Animal Experiment Center and of laboratory support areas, such as washing and sterilization rooms.

(b) purchasing protective equipment: COLLECTIVE - biological safety booths, autoclaves, Geiger counters, isothermal boxes for transporting biological material in the campus; INDIVIDUAL - face shields, nitrile gloves, disposable lab coats, PF2 shell-type masks, paper resistant to corrosive liquids for covering countertops, signage to increase laboratory safety, 3M powered respirators. Protective equipment was selected by taking into account risks involved in laboratory activities.

(c) professional capacity building: the adoption of biosafety measures does not only result in changes in the work infrastructure. Rather, it is mainly a change of principles, since health professionals tend to minimize the risks they face (MASTROENI, 2008). It is based on this principle that the Committee intends to raise awareness and promote the discussion about biosafety, encouraging thoughts about the work process. In this regard, CIBio / IOC is investing in the educational process with the Program of Professional Training in Biosafety (PCPB), whose goal is - not disregarding the social and political aspects that affect its scope of work – the individual professional training of its workforce, attempting to intervene with the institutional model of biosafety management. PCPB includes several courses / subjects - for mid-level and college degree professionals, remote teaching, subjects for post-graduate students, specific courses for the hearing-impaired - as well as seminars, workshops and lectures.

Conclusions

The subject addressed in this paper emphasizes the importance of a management process within a health care / research institution, which aims to implement and maintain high quality work in the laboratory environment, reducing the risks associated with those activities. Biosafety management should not be "cloned". Rather, it should be built with the participation of all professionals, taking into account a detailed study of manipulated agents, methods employed, available technology and infrastructure, so as to define the biosafety measures to be adopted and assessed towards the improvement of working conditions and in professional training programs in compliance with local and international rules.

Notes

1.United Nations Conference on the Environment and Development, Rio de Janeiro, 1992 (MAGALHÃES, 2005).

2.One of the main results of the United Nations Conference on Environment and Development - UNCED (Rio 92) and one of the most important international instruments related to the environment, working as a legal / political umbrella for several more specific environmental covenants and agreements (http://www.cdb.gov.br/CDB).

3.The Cartagena Protocol on Biosafety is the first agreement signed under the Convention on Biological Diversity. It aims at providing suitable levels of protection to ensure safe transfer, handling and use of living modified organisms (LMOs)

resulting from modern biotechnology, which may have adverse effects on the conservation and sustainable use of biological diversity, taking into account risks to human health resulting from the crossborder displacement (http://www.cdb.gov.br/cartagena).

4.The first references to the use of the precautionary principle in environmental matters emerged in the 1980s, with respect to protection of the ozone layer that exists around the planet, when many scientists warned about the use of chlorofluorocarbons (CFCs). In 1987, the precautionary principle has been recognized as autonomous in the Second International Conference on the Protection of the North Sea (Magalhães, 2005).

Bibliographic References

ARAÙJO JÚNIOR, R.H.; ALVARES, L. Gerenciamento estratégico da informação: a convergência a partir da Sociedade da Informação. Parcerias Estratégicas. Centro de Gestão e Estudos Estratégicos, n. 25, p. 47-66, 2007.

BORÉM, A; SANTOS, F.R. Biotecnologia simplificada. Viçosa: Universidade Federal de Viçosa, 2004.

BRASIL, Constituição da República Federativa do Brasil de 1988.

http://www.planalto.gov.br/ccivil_03/constituicao/constitui%C3%A7ao.htm. Acesso em: jan. 2008).

BRASIL, Lei no 11.105, de 24 de março de 2005. Regulamenta os incisos II, IV e V do § 1o do art. 225 da Constituição Federal, estabelece normas de segurança e mecanismos de fiscalização de atividades que envolvam organismos geneticamente modificados – OGM e seus derivados, cria o Conselho Nacional de Biossegurança – CNBS, reestrutura a Comissão Técnica Nacional de Biossegurança – CTNBio, dispõe sobre a Política Nacional de Biossegurança – PNB, revoga a Lei no 8.974, de 5 de janeiro de 1995, e a Medida Provisória no 2.191-9, de 23 de agosto de 2001, e os arts. 5o, 6o, 7o, 8o, 9o, 10o e 16o da Lei nº 10.814, de 15 de dezembro de 2003, e dá outras providências. http://www.ctnbio.gov.br/index.php/content/view/11992.html. Acesso em: nov. 2008.

CARDELLA, B. Segurança no trabalho e prevenção de acidentes: uma abordagem holística: segurança integrada à missão organizacional com produtividade, qualidade, preservação ambiental e desenvolvimento de pessoas. São Paulo: Atlas, 2008.

CIBIO-COMISSÃO INTERNA DE BIOSSEGURANÇA - Instituto Oswaldo Cruz - Fundação Oswaldo Cruz. Manual de Procedimentos Referentes à Manipulação de Organismos e Animais Geneticamente Modificados. Rio de Janeiro: IOC, 2002.

COSTA, M. A. F. Construção do conhecimento em saúde: o ensino de biossegurança em cursos de nível médio na Fundação Oswaldo Cruz. Tese de Doutorado, Pós-graduação em Ensino de Biociências em Saúde, Rio de Janeiro, 2005, p. 152.

COSTA, M. A. F. Qualidade em Biossegurança. Rio de Janeiro: Qualitymark, 2000.

CTBIO - COMISSÃO TÉCNICA DE BIOSSEGURANÇA. Fundação Oswaldo Cruz. Um cenário realista da biossegurança. Rio de Janeiro: Fiocruz, v.1, 1997.

IBIAPINA, F.L.P. Avaliando a qualidade das áreas de suporte em uma instituição de saúde - Validando um modelo a partir da POCC – Próxima Operação como Cliente. Monografia do Curso de Especialização em Administração Hospitalar da Universidade Gama Filho, 2005. Disponível em: http://www.fundacaounimed.org.br/site/Monografias/F1%C3%A1vio%20L%C3%BAcio%20Pontes%20Ibiapina.pdf. Acesso em: jan. 2009.

MAGALHÃES, V. G. O princípio da precaução e os organismos transgênicos. In: VARELLA, M.D.; BARROS-PLATIEU, A.F. Organismos geneticamente modificados. Belo Horizonte: Del Rey. p. 61-122, 2005.

MARCHIORI, M. Cultura e comunicação organizacional: um olhar estratégico sobre organização. São Cateano, SP: Difusão Editora, 2006.

MASTROENI, M. F. A difícil tarefa de praticar a biossegurança. Ciência e cultura, v. 60, p. 4-5, 2008.

MOSER, A. Biotecnologia e bioética: para onde vamos? Petrópolis: Vozes, 2004.

NODARI, R. O. Biossegurança, transgênicos e risco ambiental: os desafios da nova Lei de Biossegurança. In: LEITE, R. M.; FAGÚNDEZ, P. R. A. Biossegurança e novas tecnologias na sociedade de risco: aspectos jurídicos, técnicos e sociais. Florianópolis: Conceito Editorial. p. 17-90, 2007.

TEIXEIRA-FILHO, J. Gerenciando conhecimento. Senac, Rio de Janeiro, 2000.

VARELLA, M. D. O tratamento jurídico-político dos OGM no Brasil. In: VARELLA, M. D.; BARROS-PLATIEU, A. F. Organismos geneticamente modificados. Belo Horizonte: Del Rey. p. 3-60, 2005.

About the authors

Maria Eveline de Castro Pereira

Graduated in Business Administration from the Federal University of Rio de Janeiro (1984). She is a student for a Master's degree at the sensu stricto Post-graduate Program for Teaching in the areas of Bioscience and Health at Oswaldo Cruz Institute. Ms. Pereira is currently an S&T analyst at the Oswaldo Cruz Foundation, and her work concentrates mainly on the following areas: biosafety; professional training; biosafety management; risk assessment; and protection equipment.

Cíntia Moraes Borba

Is a biologist with a Masters' degree in Biology of Parasites from the Oswaldo Cruz Foundation (1993), and a doctorate in Biology of Parasites from the Oswaldo Cruz Foundation (2002). She is currently an Associate Researcher at Oswaldo Cruz Institute (IOC), Fiocruz, and has been a Member of the Internal Biosafety Committee of the IOC since 2002. She has experience in Biosafety and Mycology, and her work focuses mainly on the following areas: assessment and monitoring of projects involving GMOs and their byproducts; professional training; biosafety and morphology management; virulence factors; and an experimental model for studying the virulence of fungi.