



Memories of Biosafety in Brazil: Lessons to be Learned

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Introduction

The term “biosafety” was officially introduced into the Brazilian vocabulary with Law No. 8.974 of 1995—the so-called “Biosafety Law.” The discipline of Biosafety however, goes beyond the judicial scope of current Brazilian Biosafety regulations, entering into the sphere of global scientific knowledge (Brazil, 1995) since scientific papers and manuals on this topic are produced all over the world. The risk or probability of hazard is the research tenet of this new science. However, assessing the exposure risk to researchers and professionals working in labs or environments where microorganisms are present is only one of the fields of action of biosafety as a scientific discipline (ABSA, 2001; CDC & NIH, 1984, 1999; Grisht, 1995; Hirata e Mancini Filho, 2002; Oda & Ávila, 1998; Teixeira & Valle, 1996; WHO, 2003).

The studies carried out by Meyer and Eddie in 1941, followed by those of Sulkin and Pike in 1949, are the historical milestones in the process of risk assessment in activities involving biological agents. These studies resulted in the first containment and control procedures that would shape the future of biosafety. In 1979, in his classical review on laboratory infections, Pike concluded: “The knowledge of techniques and equipment for preventing the greater part of laboratory infections is already available, however without establishing rules or protocols for the management of these hazards in the lab” (Pike, 1979).

The first edition of the *Classification of Etiological*

Agents on the Basis of Hazard in 1974 (CDC, 1974) presented the criteria for biological risk assessment and the procedures for containing these hazards in an entirely new format, classifying them into four basic levels. The first Biosafety manual published by the USA’s Centers for Disease Control (CDC & NIH, 1984) refers to Biosafety as a set of procedures, practices, and equipment for minimizing or preventing hazards posed by pathogens. This publication, now in its fourth edition (CDC & NIH, 1999), as well as the *Biosafety Manual* of the World Health Organization (WHO, 2003), recognizes biosafety as a multidisciplinary science but focuses mainly on biological hazards, considering other hazards posed by the laboratory work process only as byproducts.

The criteria used in these texts to create hazard classifications for etiological agents are still used today to classify the risk levels of new agents, such as genetically modified organisms (GMOs). For example, the descriptions for Biosafety Levels 1 to 4 (BSL1 to BSL4) as a form of risk management with recombinant DNA are consistent with the original classification criteria for conventional etiological agents (NIH, 1994; WHO, 2003).

With the first DNA experiments carried out by Cohen et al. in 1972, a certain concern arose in the scientific community regarding the possible hazards associated with the so-called recombinant DNA technologies. In response, the Asilomar Conference in California [1975] established clear rules for the control of these risks and set the ethical criteria and operational procedures necessary to ensure that any

new experiments in the field of genetic engineering were ethical and safe (Berg et al., 1975). The conference was also the beginning of a series of polemics and discussions between researchers and society regarding the potential risks and benefits these techniques could bring to the development of new species (Gura, 1999).

The basic principle of biosafety is risk control and risk management. The preventive methods used to protect the researcher, the object under research, and the environment are the first step in minimizing risk and constitute the field of action of Biosafety (Oda & Ávila, 1998). Since risk involves probability, there is no such thing as zero risk; therefore, risk is a part of all scientific activity, which sets the premise for Biosafety (UNEP, 1996; WHO, 2003).

Although in Brazil the word "biosafety" was introduced into the Portuguese language through the "Biosafety Law," the definition of this field as a science became official only after the publication of the National Biodiversity Policy at the end of the 20th century (Brazil, 2000). In it biosafety is defined as "science directed to control and prevent hazards posed by the use of different technologies, be it at the laboratory, be it applied to the environment," with the basic purposes of ensuring the advance of technological processes and of protecting human and animal health and the environment.

Biosafety in Brazil: Creating Authorities and a Legal Basis

Biosafety is a relatively new and challenging field of scientific knowledge. Before 1975, little was known about procedures for the assessment and prevention of hazards, and biosafety was restricted to information about risks inherent in scientific research (ABSA, 2001). In 1980, the American Biological Safety Association (ABSA), the first scientific association in the world established to develop biosafety as a scientific discipline, was founded. ABSA provides scientific interchange in the field of risk assessment and risk management procedures, builds human resources in the field, and disseminates scientific information through publications in different areas of Biosafety (ABSA, 2003).

In Brazil, biosafety was officially recognized when the country took part in an international biosafety training program offered by the World Health Organization. The goal of this training was to expand biosafety in Latin America. As a result, in 1985 the Oswaldo Cruz Foundation offered the first course on biosafety for the health sector. At the same time, the institution started to implement biosafety measures as a part of its "Good Laboratory Practices" (Oda, 1998). These initiatives spurred the development of a number of courses and actions in the field of biosafety in Brazil (Oda, 2001). In 1991, the Oswaldo Cruz Foundation offered an advanced training course in Biosafety held at the National School for Public Health "Sérgio Arouca" (ENSP) and in 1992, biosafety became an obligatory discipline in all graduate courses at the Oswaldo Cruz Institute. In 2002, the Federal University of Santa Catarina established the first graduate course *latu sensu* in biosafety with the support of the National Research Council (CNPq) (UFSC, 2003). In 2004, the National School for Public Health offered a distance-learning course on "Biosafety in Public Health Laboratories," and in 2005, the research institute Evandro Chagas of the Oswaldo Cruz Foundation offered a graduate course *latu sensu* on "Biosafety in Health Institutions."

In 1995, the General Coordination for Scientific-Technological Development (CGDCT) of the Ministry of Health, trying to develop a strategy for epidemiological, laboratory, and clinical control of infection in Brazil, organized a workshop to discuss the Brazilian Project for Scientific-Technological Capacity Building in the field of infectious, emerging, and re-emerging diseases. This workshop led to a consensus that in order to increase the participation of Brazilian institutions in this field, biosafety principles had to become an absolute priority not only by adapting the infrastructure of these institutions but also by inducing a change in behavior through the dissemination and assimilation of new information (Rocha & Guerra, 2000). In order to accomplish this, it was necessary to know the real conditions of the country's institutions in terms of quality in Biosafety. The Biosafety Nucleus (NUBio) of the Oswaldo Cruz Foundation, where a mapping of the hazards to which the professionals working at the

units of FIOCRUZ were exposed was already in progress, was put in charge of this mission. Taking advantage of NUBio's experience, FIOCRUZ established the Scientific-Technological Capacitation Program in Biosafety in cooperation with the CGDCT [1995]. This program involved two basic activities: the mapping of hazards as original information and a plan for dealing with questions that arose. The program included the Public Health Laboratories (LACENs) of the States of São Paulo, Minas Gerais, Pernambuco, Pará, and Bahia and the regional research centers of FIOCRUZ. As a result, approximately 900 professionals participated in courses focused on proper biosafety behaviors, and questions raised and procedures developed were later discussed at each institution.

In 2000, the National Health Foundation (FUNASA), the executive body of the Ministry of Health, together with the Centers for Disease Control (CDC) and the Biosafety Nucleus of the Oswaldo Cruz Foundation created a program for mentors in biosafety. Investments in the Brazilian Central Public Health Laboratories (LACENs) and some national reference laboratories were established as a priority because these laboratories are responsible for the majority of diagnoses of controlled diseases and laboratory staff must handle biohazardous agents. At this time, three fields of action were defined:

1. Setting up programs to educate high school and undergraduate-level professionals
2. Establishing norms for institutions regarding the basic requirements for installations and equipment, creating internal biosafety commissions, and establishing good laboratory practices in the handling of pathogenic microorganisms, their shipment and transfer, and the conservation of samples
3. Adapting or building BSL 3 laboratories

In July 2000, 60 representatives from Brazil's 27 LACENs were trained in the first course for mentors. After that, three regional courses for biosafety mentors were offered so that at the end of this first phase each Brazilian state had six trained biosafety mentors. With this, Brazil is on its way to achieving its goals:

1. To establish university-level professionals in Biosafety to act as articulators among the different Bra-

zilian public health reference centers

2. To create a management and monitoring policy
3. To make available the necessary information to expand and implement control and prevention strategies

On returning to their states, these professionals started disseminating their knowledge, and this training program is still ongoing. The program has trained about 4,000 biosafety professionals throughout Brazil.

Two years after the beginning of this program, real changes could already be felt—in behavior, such as changes in habits and greater awareness of hazards, and in institutional policies, with the creation of programs for biosafety, quality, and continuing education in more than 50% of LACENs.

With the implementation of Law No. 8.974 in 1995, the Biosafety Law, the National Association of Biosafety (ANBio) was established in Brazil. This nongovernmental multidisciplinary organization promotes biosafety as a field of knowledge and disseminates information using both the American Biological Safety Association (ABSA) (ABSA, 2003) and the European Biosafety Association (EBSA) (EBSA, 2003), with which ANBio is affiliated, as its example. ANBio participates in the international meetings and scientific publications of both associations, providing a permanent interchange of Biosafety information among the countries. During its six years of existence, ANBio has organized three international congresses, three Latin American symposia, the National Biology Olympiad with more than 6,000 registrants and a number of courses, and has trained more than 3,000 professionals in the country and supports courses at some Brazilian universities (ANBio, 2003; UFSC, 2003).

Law No. 8.974 and its revised 2005 version created the National Technical Biosafety Commission (CTNBio), linked to the Ministry of Science and Technology (MCT). However, Law No. 8.974 refers only to Biosafety involving GMOs and their derivatives. Its actions are restricted to the handling of genetically modified organisms. At present there is a gap in regulation with respect to nongenetically modified pathogenic organisms. The definition of norms and the creation of directives regarding the manipulation, storage, shipment, and discard of

nongenetically modified pathogenic organisms is of great interest for the Unified Health System (SUS), its research units, and health services because their professionals are continually exposed to the risk of contamination.

In February 2002, the Biosafety Commission in Health (CBS) was created as part of the Ministry of Health. The Commission is presently coordinated by the Secretariat of Science, Technology, and Strategic Health Products (SCTIE) through the General Coordination of Biotechnology in Health (DECIT). Besides representatives of the latter, the Commission is composed of the Secretariat of Health Vigilance (SVS), Secretariat of Health Care (SAS), the Department of International Affairs in Health (AISA), the Oswaldo Cruz Foundation (FIOCRUZ), National Foundation for Health (FUNASA), and the National Agency for Health Control (ANVISA). Its purpose is to define strategies for the assessment and monitoring of actions related to biosafety. It discusses and proposes ways to gain uniformity of concepts and actions throughout the country, contributing to the integration of this ministry with other institutions dealing with this subject.

Its main tasks include:

- Participating on both national and international levels in the reformulation of Biosafety norms, with the goal of establishing legal instruments that reach beyond genetically modified organisms (GMOs) to the entire scope of biological risks
- Conducting a survey and analysis of questions related to Biosafety in order to identify its impact on and correlations with human health
- Proposing studies to assist the Ministry of Health in decisions regarding biosafety-related questions

CBS started its work by revising the “classification of disease-causing agents for humans and animals on the basis of hazard.” It also worked to elaborate on biosafety norms on the manipulation of pathogenic agents in the laboratory, including procedures, storage, shipment, and discard of risk material; to establish basic principles for the construction/redesign of labs of different Biosafety levels including those involved with animal experimentation; and to compose a legal instrument requiring all health units to create internal Biosafety Commissions.

In order to create this legal framework and put it

into practice throughout the country, it is necessary to strengthen continuing education programs in biosafety, increase professionals’ awareness regarding risk situations, and introduce new behavioral standards. Furthermore, it is also necessary to develop research in the field of risk assessment and risk management and to foster initiatives for the dissemination of information and scientific interchange between Brazil and other countries so that Brazil can incorporate technological advances quickly and be competitive within the international market.

The Building Process of the Brazilian “Biosafety Law”

The new knowledge created by biotechnological research since the 1970s has caused the public increasingly to think about the impact this new technology will have upon society. Various government entities and economic sectors began to ponder how to promote, manage, and monitor the results of this research. This scenario provoked movements in support of the benefits of biosafety, as well as others with adverse reactions, as happens with every technological innovation going beyond common knowledge (Kinderlerer, 1997).

Moreover, the development of new technologies also engenders controversy. One might argue, for example, that nonreproductive cloning and the use of stem cells should not be rejected as a therapeutic aid. Such a decision, however, must be made with common consent from lawyers, politicians, religious leaders, and representatives from associations of carriers of genetic diseases. Although most are, in principle, against reproductive cloning, however, many Brazilians defend therapeutic cloning. (This issue is further analyzed in the *Code of Ethics in Genetic Manipulations* (Brito-Filho & Dias, 2002). However, with the advancement of new technologies, Brazil’s Biosafety regulatory system has to be periodically reviewed. This occurred recently when Law No. 8.974 was reviewed and a new law, Law No. 11.105, (March 2005), was put into effect. This new Biosafety law now allows the use of stem cells obtained from embryos for therapeutic purposes, although therapeutic cloning is still forbidden.

Because the organizational structure of Brazil allows its citizens to put into place effective and rigorous controls concerning the possible risks of recombining DNA and other modern biotechnology, biosafety is understood within the Brazilian legal system as a set of measures allowing the safe use of genetic engineering and other experiments arising from this field of knowledge (for example, laboratory and field experiments with transgenic organisms and gene therapy research). In this way, the Brazilian legal apparatus is specific for a certain segment of technology but does not apply to all activities involving risk *per se* (Brazil, 1995; Brazil, 2005). For the risk assessment of GMOs, according to Brazilian legislation, the country must strive to reach the standard of international quality. The authorization to plant and commercialize a transgenic variant, for example, is the result of much laboratory and field research involving years of work. Different important steps of risk assessment and application of biosafety concepts are required to come to a final conclusion about the safety of such a product (Oda, 2001).

Although every country has its own distinctive biosafety policy, three factors are common to all:

1. The need to train those involved in biosafety endeavors
2. A specific legal background and code of operation
3. The necessary infrastructure for research and technological development

There are two legal models for risk assessment of products produced with recombinant DNA technology. One is based on the final product without considering the production method, as used in the United States and Canada among others. The other model considers the production process and establishes a specific legal structure demanding a case-by-case analysis of every product originating from recombinant DNA technology. This last model is the one adopted by the countries of the European Union, Australia, Japan, China, and Brazil.

After the accelerated development of biotechnology in the 1970s and 1980s, the 1992 Convention on Biologic Diversity crafted a multilateral agreement for the safe promotion and development of modern biotechnology which was signed by various countries. Immediately after that, the United Na-

tions Environment Program published the first international directives for safe procedures in the field of biotechnology (UNEP, 1996).

Before the international community addressed the need for caution in the use of recombinant DNA technology, Brazil enacted a specific regulatory model approved by its national congress in 1994—the draft law proposed by Senator Marco Maciel which, similar to the European model, only governed genetic engineering activities within the country (Kinderlerer, 1997). This logic—ruling the technology but not the product—is maintained in the new version of the Biosafety Law of March 2005 (Brazil, 2005).

Law No. 8.974 of 1995 had been backed by the Executive Power but suffered two vetoes due to articles 5 and 6 that created the National Technical Biosafety Commission (CTNBio) and linked it to the Presidency of the Republic. Law No. 8.974 was created in accordance with article 225 of the Federal Constitution, which refers to the protection, and preservation of biological diversity and health. The vetoes of the Executive Power against the law approved by the National Congress led later to juridical conflicts between Biosafety and Environmental legislation. The issue centered on whether CTNBio was entitled to establish a Previous Study on the Environmental Impact (EIA) for GMOs as a legal obligation (Oda, 2002). To settle this controversy and in an attempt to preserve the role of CTNBio, the vetoed items regarding risk assessment of biotechnological products were incorporated into provisional measure No. 2191-9 (Brazil, 2001).

Provisional measure No. 2191-9 introduced some innovations to the GMO regulation, defining administrative procedures and the ethical mission of CTNBio. In addition, it:

- Reaffirms the ethical mission of the Commission
- Emphasizes the role of the sectorial subcommissions in the proposed new regulation
- Unifies the technical conclusions of the Commission so that they are respected by the represented ministries
- Affirms and clarifies the authority of the Commission to identify potentially environment-degrading activities, thus settling the conflict with

the environmental legislations

- Defines the responsibilities of the ministerial organs in charge of authorizing and registering each GMO.

Even with provisional measure No. 2191-9 in force, lawsuits continue and the Brazilian government continually submits new legal documents to the National Congress to better elucidate the authority of the different regulating agencies. In February 2005, after a discussion of nearly 2 years, the National Congress approved the new Brazilian “Biosafety Law” sanctioned by the President of the Republic in March 2005 as Law No. 11.105. This regulation regarding the biosafety of GMOs follows the precept of precaution, recognizes biosafety as a multidisciplinary activity, counts on organized participation by multiple aspects of society, and encourages case-by-case risk assessment on a scientific basis.

The precept of precaution is of extreme importance in the use of these new biotechnologies because it encourages dialogue about the social, economical, political, cultural, and environmental benefits as well as the potentially enormous problems depending on the choice and application of biosafety benefits. It must be emphasized that this precept emerged from an international context as a consequence of a history of aggressive use of innovative technologies applied in the name of progress and development that caused environmental and social damage by manipulating scientific knowledge. This resulted in what we today call the “risk society,” which is expressing doubts about the absolute power of science and technology based on its concerns with environmental questions and their consequences for society.

The debate involving the use of modern biotechnology in Brazil and its legal background gives enormous relevance to the precept of precaution. According to Mialhe (2004), this precept serves as a shield against the abuse of technology, but it simultaneously creates an obstacle for innovation. In this context it should be pointed out that precaution must not be understood as a systematic recommendation to abstain. Although usually not understood this way, it should be perceived as a *motivation* for action. Contrary to the principle “when in doubt, abstain,”

the precautionary principle recommends “when in doubt, act in the best way possible.” This positive attitude—active much more than inactive—corresponds to the greater purpose of reducing the risks for humankind and the world environment. The precept of precaution does not renounce the expected benefits of technological development. In fact, it states that in adopting certain measures to prevent trouble that may arise from technological development, it is taking care that any residual risks are acceptable compared to the benefits. Precaution cannot be seen as an irrational demand for zero risk; it is meant as an assessment of the seriousness of the risks and their probability to occur. On the basis of this information we must be alert not only with the decision to act or not but also with the resolve to follow-up the consequences of the choice we make (Mialhe, 2004).

The Role of the National Technical Biosafety Commission (CTNBio) in the Process of Risk Assessment of GMOs

CTNBio is linked to the Ministry of Science and Technology, which started its activities in 1996. CTNBio’s members and their substitutes are highly renowned scientists specializing in human, animal, vegetal, and environmental health, who are supported by scientific societies and the academic community and who are representatives of the ministries related to this area.

From 1998 on, after the CTNBio first authorized the commercialization of a transgenic crop, research on genetically modified organisms (GMOs) in Brazil slowed down considerably as a result of the insecurity caused by lawsuits against this decision. The central point of the discussion was who was in charge of the risk assessment for these organisms—CTNBio or another control authority from the ministries. To put an end to this polemic caused by the legal debate, Law No. 8.974 was updated and in 2005 the new Law No. 11.105 established two deliberative bodies: CTNBio, responsible for the final risk assessment of GMOs; and a council of ministers responsible for analyzing the socioeconomic suitability of commercial introduction of a GMO in the country.

The GMO evaluation method used by CTNBio is a specific, case-by-case study of each genetically transformed product. The applicant has to submit an analysis of the safety of the GMO as well the data necessary for a technical assessment. CTNBio can also demand more information and additional tests when considered necessary.

The technical expertise for each event has to consider:

- Risks to the environment
- Risks from an agricultural viewpoint
- Risks for human and animal health

CTNBio is not legally entitled to analyze any socio-economic aspects because these fall under the responsibility of the ministries that give the final authorization for the proposed activity.

Biosafety management has to take into consideration that Brazilian society needs sustainable development through biotechnology in order to create social goods needed by society. In this context, Biosafety is an indispensable instrument for the solution of questions related to health, food, and the environment, but it should not serve as a barrier or favor international commerce.

With the new Biosafety law, the authority of each agent in the decision about Biosafety of GMOs according to the Brazilian model (Council of Ministers and CTNBio) is now clearly established in the national legislation. The role this technology plays in the improvement of agriculture and in the field of medicine is not currently in discussion. The research in this area must be strengthened in order to elucidate doubts expressed by different segments of society and to develop ways to use these products safely. In this way Biosafety will contribute to the advancement of modern biotechnology and its sustainable use in Brazilian society and will encourage the country to be more competitive in the international market.

Conclusions

Today, the final implementation of the Brazilian Biosafety law for the manipulation of GMOs hinges on a public and judicial understanding of the role of CTNBio and on Brazilian society and government's acceptance of the regulative model established by the National Congress. The 5-year delay in the imple-

mentation of a national Biosafety policy is primarily due to a lack of political consensus in the government sphere and, in the judicial sphere, to the difficulties of interpreting the analyses of different legal instruments (ANBio, 2003). Thus, an ethical, cohesive, and uniform political position must be urgently taken, independent of the model the country may choose in the future. We must avoid insecurity that could lead Brazil to obscurity and to holding back biotechnological research in its different fields.

Biosafety today is accepted as a new field of scientific knowledge, not only in Brazil but also in Europe, the United States, Canada, Latin America, and Asia (UNIDO, 2003). The consolidation of this discipline as a science in Brazil depends on national investments in the expansion of human resources in this area, scientific research in the field of risk assessment, and in socializing scientific information.

The socialization of scientific information is anchored in the idea of constructing a better dialogue between the achievements of biotechnology and the doubts and expectations of society. According to Sala (2005), its transversality goes beyond the different fields of the law and involves scientific questions and different branches of knowledge, all of which influence consequences that impact the life of each individual. Sala emphasizes:

“...although the experts may help to elucidate technical-scientific information, they are not better equipped than the public when it comes to apprais[ing] the values inherent to the choices of public policy.... Even experts being generally better judges of the risks, only the public offers serious hope for the construction of an informed society, necessary for an efficient risk management on the long-term.... The legitimacy of political decisions regarding the environment lies not only in their pertinence, but equally in the process by which these decisions were made. Those who are supposed to take the risks, did they have the opportunity to say if they consider them acceptable?” (Sala, 2005).

Since global societies are a phenomenon of our time, our sense of citizenship has led different social actors to organize themselves with the aim of influencing the decisions about new technologies and special biotechnology and its correlation with Bio-

safety, and to endorse their development and visibility. In this context the media gain an important role in nourishing the debate between science and society through quick dissemination of information and by translating the information into languages that allow social participation worldwide through forming public opinion and highlighting individual rights. From this debate we understand the importance of Biosafety information for decision-making as well as the need for suitable support services. The interchange with national and international groups through networks and discussion forums contributes to a deepening of these questions and creates complexities that influence political decisions and the creation of legal structures.

The emphasis given to a participative role for the citizen in regard to biotechnology and Biosafety issues can be seen as a particular manifestation of power increasingly present in modern societies. Social scientists emphasize that the direction chosen by different social groups in our present society is not so much due to cohesion but to active information of free individuals. The way social groups organize and manage knowledge and information depends on their ability to construct knowledge and freedom of choice, which are influenced by the social and economical context of the moment. Thus, a greater engagement and participation of the citizens in understanding the benefits but also the adverse effects of biotechnology and of Biosafety are necessary. The participants reject or incorporate the essence of the discussions—the emotion, opinions, and attitudes that build the elements to construct social representations. Accept and agree or reject make it possible to build upon individual and collective opinions reflected in the construction of political and social awareness.

The role played by organizations is consolidation, by this field of knowledge by providing an interchange between similar associations in the world and accelerating scientific-technological development is thus fundamental. The model chosen by Brazil for regulating Biosafety procedures for the manipulation of GMOs should be understood and supported by our citizens because it represents a safe way of accepting new technologies and simultaneously to model international standards.

Unifying broad and fundamental bases, the social actors try to identify solutions for emerging

problems and make efforts to reduce obstacles to a quick and effective application of biotechnological research so that the results are quickly available to society. The work of promoting life and the environment is done by motivating integration of biotechnological advancements and Biosafety, based on good quality of health services, concern with the environment, and dissemination of information for the general public about the decisions made in the governmental sphere. A thorough understanding of the legal and political aspects as well as the information system helps individuals to choose consistently, based on their cultural, familial, and personal values.

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