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BIOSAFETY REGULATIONS IN BRAZIL

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ABSTRACT

Introduction of biosafety regulations in Brazil is recent. The newly approved law presents a backbone format, allowing for future and fast changes of issues related to the release of genetically modified organisms. This paper presents the major aspects of the regulations and reasons for setting up the new law.

Key Words: **Biotechnology, genetically modified organisms, transgenic plants**

RÉSUMÉ

La mise en place de règles de biosécurité est tout à fait récente au Brésil. La nouvelle loi qui a été approuvée constitue un cadre qui permet de tenir compte des changements rapides et futurs relatifs à la diffusion d'organismes génétiquement modifiés. Le papier présente les aspects majeurs et les raisons de mise en place de la nouvelle loi.

Mots Clés: **Biotechnologie, organismes génétiquement modifiés, plantes transgéniques**

INTRODUCTION

Biosafety issues began to be discussed in Brazil in the late 1980s. In 1990/91, based on the National Academy of Sciences' experience (NAS, 1987) some minimum laboratory guidelines were set up as a requirement for having a project approved for funding by a special programme, the Support Programme for Science and Technology (PADCT) run by the Brazilian Ministry of Science and Technology. However, it was only in November 1992, after a meeting in Argentina, sponsored by the Inter-Amer Institute for Cooperation on Agriculture (IICA) to discuss the harmonisation of biosafety regulations for transgenic plants in the countries of the Southern Cone, that scientists really decided to work towards a legislation to provide means for the safe release of genetically modified organisms (GMOs).

As happened in other countries, and after the conclusions and recommendations of the IICA meeting in 1993 (IICA, 1993), scientists and regulators had decided that the best approach would be for the Ministries of Agriculture, Health and Environment to amend already existing regulations to include issues related to the safe handling of GMOs. After a careful study of the situation, however, it was clear that a new law, specifically regulating the use of new biotechnologies and GMOs, was the only way

forward because such a law had already been sent to Congress early in 1991.

During 1994, a group of scientists representing the Ministry of Health (Fundaçao Oswaldo Cruz-Flocruz) and the Ministry of Agriculture (EMBRAPA/CENARGEN) worked on the final text of the law which was approved by Congress and published in January 1995. The Ministry of Science and Technology proposed some amendments and changes to the composition of the National Biosafety Committee which will delay full implementation until later in the year. The newly approved law (No. 8974) presents a backbone format, allowing for fast future changes of the issues related to the release of GMOs. Regulation as provided by the National Biosafety Committee can be improved and altered as the available knowledge on risk assessment increases with the number of field experiments being developed in different countries of the world.

MAJOR ASPECTS OF THE LAW

The major aspects of the law are as follows: (1) Creation of a National Biosafety Committee (CTNBio), under the Ministry of Science and Technology, to study and implement the regulations within the scope of the law. This body will be formed by eight scientists working in the area of modern biotechnology and concerned with biosafety issues, plus six members nominated by the Ministries of Health, Agriculture, Environment, Education, Foreign Affairs and Science and Technology, and three members nominated by other organised groups including private industry. (2) Members will serve renewable 3-year terms, and decisions will be made by a minimum of two-thirds of the members. (3) Among its main activities, the CTNBio will, during 1995/96, prepare National Biosafety Guidelines, a National Ethical Code for Genetic Manipulations, provide means for the implementation of the Institutional (Internal) Biosafety Committees (CIBios), and certify each of the laboratories which is already working or will work with transgenic material. (4) Each Ministry which has under its responsibility any laboratory working with GMOs will have to provide trained personnel to monitor its laboratory and field activities. (5) When working with biotechnological tools, the following are now prohibited: manipulation of germinal human cells; *in vivo* intervention on human genetic material unless for the cure of genetic defects; and the production, storage and manipulation of human embryos as part of experimental disposable material. Prohibition also covers *in vivo* intervention on animal genetic material unless for the progress of science and technology, subjected to prior approval by the CTNBio; and the discard of any genetically modified material unless in accordance with regulations provided for in the laws.

According to the text of Law No. 8974, GMOs are classified in two major Risk Groups. Group I consists of receptor or parental organisms which are non-pathogenic and have a well documented literature showing their lack of negative effects to the environment; and vectors with well documented interaction with the environment, small and well characterised in size, with well known functions, non-mobilisable, and without any transmissible resistance marker which cannot be acquired under normal conditions. It also includes microorganisms entirely constructed from only one pro- or eukaryotic receptor, or organisms entirely composed by genetic sequences of different species but which exchange such sequences by known physiological processes. Group II consisting of organisms with characteristics different from those described in Group I.

For the introduction of GMOs in Brazil, any government or private laboratory will have to obtain permission from the relevant Ministry or from CTNBio and the Ministry, according to the classification of the request within Group I or II.

As of September 1995, every governmental research institute or private company working with GMOs will have to submit to the CTNBio the composition of its Institutional (Internal) Biosafety Committee (CTIBio) and specify the principal researcher for each project who will be bound by the Law for the safe implementation of the activities. The CTIBio is also responsible under the Law for the safe implementation of the activities and any related activities, and for the submission of any proposal to the National

Committee. It shall monitor and notify the National Committee and competent authorities in case of any harm to people or to the environment.

Any action violating the items described above or other detailed items described in the original text of the Law, are now considered a crime. Penalties vary from a US$ 10,000 fine to twenty years in jail according to the degree of violation.

To advance in the regulations to be provided by the National Biosafety Committee, CENARGEN's Internal Biosafety Committee has begun a study of available international guidelines for the release of GMOs and has come up with a questionnaire adopted to national conditions. It is based on the guidelines published by the Genetic Manipulation Advisory Committee of Australia (GMAC, 1993).

It may seem that a complex law such as the one approved will complicate matters and impose extra barriers to field tests which should begin later this year. However, regulatory authorities have decided to take these steps because Brazil is located in the tropics, has six different ecosystems represented within its territory, and is concerned about the effect that the large commercial scale release of externally produced GMOs may have on the biodiversity of the region. Major cultivated plants such as potato, cassava, pineapple, groundnut, squash, sweet potato, tomato, lima and French beans, cacao, papaya maize and chili/ pepper have their centres of origin in the Mexican, South and Central American regions (FAO, 1993). The ecological risks of introducing genetically engineered plants into centres of diversity have not been well studied.

The inauguration in January 1995 of integrated open markets, such as MERCOSUL, in the region with free access to commercialisation of products, is a very worrying situation which is at present being discussed by federal authorities. The importance of harmonising biosafety regulations among the countries of Latin America and the Caribbean has never been so urgent. Action in this direction was already taken by IICA after a meeting held in Cartagena, Colombia, in 1994. It proposed a set of minimum regulations to be followed by those countries which are part of the Andean Region (IICA, 1994). During 1995, another regional meeting should unite the views of the Caribbean countries. Developing countries expect the Conference of the Parties to the Convention of Biological Diversity to discuss the basis of a protocol to be considered by all countries which have signed the Convention.

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