

Embrapa's Biosafety Network

15

*Mônica Cibele Amâncio*¹, *Maria José A. Sampaio*² and *Deise Maria Fontana Capalbo*³

¹Embrapa Headquarters – 70770 –901 - Brasília / DF /Brazil monica.amancio@embrapa.br;

²Embrapa Headquarters – 70770 –901 - Brasília / DF /Brazil zeze.sampaio@embrapa.br;

³Embrapa Environment – CP 69, 13820-000, Jaguariúna /SP /Brazil deise@cnpma.embrapa.br.

ABSTRACT

Embrapa (Brazilian Agricultural Research Corporation) has been working in the biotechnology area since 1981. In 2002, Embrapa, in association with FINEP – MCT (Brazilian Ministry of Science and Technology), received a major grant to implement a research proposal aimed at evaluating the food and environmental security of genetic modified products. Following, Embrapa's Biosafety Network was created involving the coordinated work of 123 Embrapa researchers and nine other institutions of top Brazilian Universities. Embrapa conducts research strictly following all aspects of Brazilian regulation. It was the first institution to obtain the environmental license needed in order to perform experiments involving OGM release in the Brazilian environment. The Brazilian regulatory framework related to biosafety has revealed itself as extremely complicated and somehow inefficient. The main law that regulates this issue is Lei nº 8.974, from 1995. However, due to the conflicts that followed the first commercial release of OGM in Brazil, which took place in 1998 (soybean resistant to glifosate), the country now has a very complex legal arrangement around this issue. At the present time, the parliament is busily arguing about a new legislation to rule the subject, but the discussion is not finished yet. Despite all the difficulties we had faced, especially due to the hindrances associated to our domestic regulatory system, Embrapa's Biosafety Network was successfully created is now in place. Its first results are promising and we strongly believe that this network will soon reach its goals and will be the reference point of discussions about biosafety in Brazil.

INTRODUCTION

Embrapa (Brazilian Agricultural Research Corporation) has been working in the biotechnology area since 1981. The portfolio of GM plants developed since this, with many partners, includes different genes inserted into Brazilian crop cultivars for specific features. However, these GM crops must comply with the biosafety law requirements to ensure that they present the necessary level of food safety and quality, contributing to agriculture sustainability.

The Brazilian regulatory framework related to biosafety has revealed itself as extremely complicated and somehow inefficient. The main law that regulates this issue is the Law 8.974/95, but the country now has a very complex legal arrangement around this issue. Brazil has been a hot pan of discussion over the potential benefits and risks of genetically modified organisms (GMO). Safety, competitiveness, development, intellectual property rights & public goods are issues being discussed by scientists, industry proponents, NGO's, Government and policy officials, and congressmen, to mention some.

Within this scenario, the Brazilian Agricultural Research Corporation – Embrapa – recognized the need to contribute to the development of a genetically modified (GM) organisms, environmental risk assessment and food safety platform due to the urgency of in-country produced safety results and the importance of carefully designed research protocols that can meet the confidence standards by decision makers and the general public. In this direction, in 2002, Embrapa, in association with FINEP – MCT (Brazilian Ministry of Science and Technology), received a major grant to implement a research proposal aimed at evaluating the food and environmental security of genetic modified products, which aim to contribute to a more constructive and interactive biosafety analysis, presenting data that refer explicitly to specific crops, genes, ecological settings and production systems.

There are many GMOs under development in the laboratories of Embrapa's 38 Research Stations, but only those which "elite" event had been identified till 2001 are part of this project. They are:

- Papaya (*Carica papaya* L.) resistant to *Papaya ringspot virus* (PRSV)
- Bean (*Phaseolus* sp.) resistant to *Bean golden mosaic virus* (BGMV)
- Potato (*Solanum tuberosum* L.) resistant to *Potato virus Y* (PVY)
- Cotton (*Gossypium hirsutum* L. r. *latifolium*) resistant to insects
- Soybean (*Glycine max*) tolerant to herbicide (glyphosate)

Embrapa's Biosafety Network was created involving the coordinated work of 123 Embrapa researchers and nine other institutions of top Brazilian Universities. This network is called **BioSeg**. The key elements in the **BioSeg** are:

- ✓ to develop and implement biosafety protocols through a dynamic network, involving capacities already established (Embrapa and partner institutions);
- ✓ to improve scientific communication within complimentary knowledge areas;
- ✓ to allow a quick and frequent review of the proposed methodology and analysis of the GM-plants, by the network specially incorporating new important aspects for human and environment safety as soon as they are detected by any national or international groups.

With the development of **BioSeg**, some results and impacts can be expected.

Direct impact: Embrapa will have enough data to submit to national authorities for consideration of safety (food and environment safety) on some of the GM crops under study, allowing Embrapa to make a petition for their experimental field release at first and probably for their commercial release in a later phase.

Indirect impact: once established, the network, with the acquired experience, will be a reliable group for further consultation within the Country, which will be able to rapidly organize a discussion and prepare a robust report previewing impacts of other GMOs under development.

MATERIALS AND METHODS

The project has been designed in such a way as to promote cooperation. The managing, administrative and research structure is based on:

- ✓ an Executive Committee composed of one principal project coordinator, two adjunct coordinators, each Subproject Leader and two executive secretaries, that is supposed to deal with the disbursement of funds, interactive research meetings, progress reports, administration of conflicts, policy implementation, preparation of files for Government authorities and media contact;
- ✓ Subproject Leaders (one for each GM crop) who are responsible for the respective Crop Core Group that develops and reports on the experiments.

Initially based on the need to provide the data required by the National Technical Biosafety Committee, the group also pays attention to the identification of training needs and to the increasing demand for better public awareness. *BioSeg* relies on the existing capacity within Embrapa Centers (12 Research Centers and Service Centers, established in different regions of Brazil, are involved till now). Besides this, well-known national and international experts from Universities and other Research Institutes provide valuable collaboration. All together they constitute a multidisciplinary team to study the selected GM crops mentioned before – beans, papaya, potato, cotton and soybean.

The *environmental risk assessment* team aims to evaluate the impact of each GM-plant on organisms (target and non-target, crop-associated biodiversity) within the cultivated area of each crop, above and below ground effects, considering the production system in use and the specific agro-ecosystem. The *food safety group* studies factors like: composition, effects of processing and cooking, protein expression product of the novel DNA (effects on function, potential toxicity and potential allergenicity), and other aspects. Laboratory and field tests are proposed under the Brazilian regulatory system.

Both environmental and food safety studies will be extended depending on the nature of the differences/impacts=

RESULTS

Embrapa conducts research strictly following all aspects of Brazilian regulation. For the past fifteen years, in Brazil, a range of other issues have been associated with the use of biotechnology in such a way that lately politicized discussions dominate the scenario and science seldom prevails in the final considerations. Due to the conflicts that followed the first commercial release of OGM in Brazil, which took place in 1998 (soybean resistant to glifosate), the country now has a very complex legal arrangement around this issue. At the same time in Brazil there was an “illegal” expansion of transgenic soybeans.

At the present time, the parliament is busily arguing about a new legislation to rule the subject, but the discussion is not finished yet.

Despite all the difficulties, the **BioSeg** was the first institution to obtain the environmental license needed in order to perform experiments involving OGM release in the Brazilian environment.

However, these licenses were obtained a little late. The experiments of **BioSeg** were made this year and the first results were obtained now. Although they are promising, they aren't concluded yet.

DISCUSSION

The rapid advances in modern biotechnology will shape the coming decades of economic development. As more GM crops and products are field tested and eventually approved for commercialization, scientists will also learn more about how to manage the risks and the socioeconomic implications. As more developing countries begin to evaluate the in-house applications of the technology, each country will have to develop its own approach for societal discussion.

The coming years, in particular for the case of Brazil, will be a challenging period to address issues such as the need for better training of scientists (including in the areas of risk assessment and monitoring of GM-experiments) and in-house investments needed to continue the development of capacity in the area of biotechnology.

A biosafety network like the one being developed by **BioSeg** at Embrapa, can strengthen the consideration of critical problems, addressing them, with greater confidence, to predict potential positive and negative environmental and food safety impacts.

BioSeg will soon reach its goals and will be the reference point of discussions about biosafety in Brazil.

Acknowledgements

The BioSeg Project is supported by Embrapa (linked to the Ministry of Agriculture) and by FINEP / Biotechnology Fund (financial agency linked to the Ministry of Science and Technology).

The authors thanks the core group of the project for their collaboration in different steps of the development of the Bioseg, especially the Leaders and members of the Executive Committee: *Marilia R. Nutti, Eliana M. G. Fontes, Josias C. Faria, Paulo Meissner, André N. Dusi, Mariângela Hungria and Edson Watanabe.*