

THE INTERNATIONAL SERVICE FOR THE ACQUISITION OF AGRI-BIOTECH APPLICATIONS' BIOSAFETY INITIATIVE

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ABSTRACT

Biotechnology as a tool for improving agricultural production is a priority for many developing countries. Access to these technologies and the products derived may be limited due to a lack of biosafety regulations. The International Service for the Acquisition of Agri-Biotech Applications' (ISAAA) strategy is to assist developing countries to build their regulatory oversight mechanisms in a flexible approach. Workshops enable scientists and regulators to share their experiences with experts from countries with biosafety regulations in place. ISAAA brokered projects provide the opportunity for scientists involved to implement regulations with the assistance of experienced counterparts. Individual country support is targeted at country specific problems that prevent full implementation of regulations. Through ISAAA *AfriCenter*, Africa has access to the experience and expertise of ISAAA and the network built up.

Key Words: Biosafety regulations, ISAAA

RÉSUMÉ

La biotechnologie en tant qu'instrument pour l'amélioration de la production agricole, est une priorité pour beaucoup de pays en voie de développement. L'accès à ces technologies peut être limité par le manque de règlements de biosécurité. La stratégie d'ISAAA est d'assister des pays en voie de développement à établir leurs mécanismes de surveillance dans le cadre d'une approche souple. Des ateliers permettent aux scientifiques et aux régulateurs de partager leurs expériences avec des experts venant des pays qui ont des règlements de biosécurité en place. Des projets négociés par ISAAA donnent l'occasion aux scientifiques concernés d'exécuter des règlements avec l'aide des homologues expérimentés. L'appui aux pays individuels est orienté aux problèmes spécifiques des pays qui empêchent l'exécution complète des règlements. Par l'intermédiaire d'ISAAA *AfriCenter*, l'Afrique a accès à l'expérience et à la compétence d'ISAAA et à l'établissement d'un réseau.

Mots Clés: Règlements de biosécurité, ISAAA

INTRODUCTION

The International Service for the Acquisition of Agri-biotech Applications (ISAAA) was set up to assist developing countries in the acquisition and transfer of proprietary biotechnology applications (James, 1991; James and Krattiger,

1994), thus responding to the priorities and policies of many developing countries to develop biotechnology capabilities to enhance sustainable agricultural production and to limit the technology gap with industrialised countries. The objectives of ISAAA involve the building of new partnerships between technology donors and

recipients, from the public and private sector, based on results orientated and demand driven projects.

THE ISAAA BIOSAFETY INITIATIVE

Access to biotechnology application for developing countries, and in particular to recombinant DNA products, may be limited due to a lack of regulatory oversight for testing the environmental safety of these products. For projects brokered by ISAAA that involve transgenic plants, ISAAA ensures that products are tested and introduced in a safe and effective way. To address the issue of regulatory oversight, ISAAA has developed a flexible approach including workshops, technology transfer projects and individual country assistance.

WORKSHOPS

The International Service for the Acquisition of Agri-Biotech Applications has organised a number of Biosafety Workshops, bringing together scientists, administrators and policymakers from developing and industrialised countries. The first workshop was held in Costa Rica in 1992, followed by a workshop in Argentina in the same year, and Indonesia was the host country for a regional workshop in 1993. Through case studies presented at these workshops, participants, representing national biosafety committees, were provided with 'hands-on' experience and could interact with experts from countries with well established biosafety regulations. The ISAAA approach is specifically targeted at building institutions fitted to the needs, and resources, of the developing countries. Therefore, experts were invited from a range of industrialised countries, to enable developing countries to discuss systems most suitable for their situation. Countries that benefited from these workshops are: Mexico, Costa Rica, Argentina, Uruguay, Paraguay, Brazil, Malaysia, Thailand, the People's Republic of China, Indonesia and the Philippines.

While regulatory oversight in testing

transgenic plants is developing rapidly in South East Asia and Latin America and the Caribbean, the interest in African countries is increasing (Krattiger, 1994). The present workshop is a response to the need in Africa for capacity building on a national and regional level in this area. Global developments in biosafety provide the opportunity for Africa to benefit not only from the experiences of countries in the north, but also of countries in the south, which have adopted regulations that fit their specific needs.

PROJECT DEVELOPMENT

Although workshops can provide an invaluable contribution to the development of regulatory oversight, implementation of the regulations is a different step. For the implementation of biosafety regulations, an actual example of an application for field trials, for instance of a transgenic plant, is essential to test the efficiency of the regulatory system. Through projects involving transgenic plants ISAAA is assisting countries in this implementation phase. Four of the countries involved in the workshops have already had the opportunity to benefit from partnerships with industrialised countries to implement their regulations through ISAAA brokered projects, whilst in other countries ISAAA assists in introducing requested transgenic crops (Raman, 1994).

One specific example is the ISAAA brokered project for technology transfer to Mexico, involving potatoes transformed with non conventional virus resistance genes. The distribution of improved potatoes to farmers, which is the final target of the project, involves different steps: (1) identification of major areas of improvement of germplasm-virus resistance in conventionally grown varieties of potato; (2) identification of applicable technology to achieve improvement in conventional virus resistance by transformation with coat protein; (3) identification of recipient and donor of the technology, and financial donor-CINVESTAV, in Mexico being the recipient, Monsanto (USA) technology donor, and Rockefeller Foundation financial donor; (4) training of a Mexican scientist in the USA in basic transformation techniques; (5) adaptation of vectors and

regeneration protocols for specific Mexican potato germplasm and production of transgenic plants and biosafety issues concerning contained use; (6) training of a Mexican scientist in field testing of transgenic plants in the USA; (7) field tests in Mexico and biosafety issues concerning field release; (8) multiplication of selections through tissue culture and discussions with biosafety committee to hand over material to growers for multiplication and field trials; (9) training of Mexican growers in potato seed production in the USA; and (10) multiplication of selections by growers.

To date, four years after the start of the project, plans for commercialisation are under consideration. Through these types of projects, owned by the national programmes many countries have benefited from the documentation derived specifically from the workshop in Costa Rica (Krattiger and Rosemarin, 1994). Implementation of regulations is achieved by capacity building, assisted by the experience of the technology donor. The next regulatory issue to be addressed in this project, as it concerns a food crop, is food safety. Since food safety, for example, toxicity and allergenicity, is not related to environment, data generated at different places in the world can be utilised on a global basis, giving an excellent opportunity for harmonisation and international data acceptance. ISAAA's strategy in food safety will be similar to biosafety: workshops to enable sharing of experiences, and implementation through technology transfer projects.

Projects similar to the described potato project, driven by a need for specific products, but addressing the capacity building in biotechnology, biosafety and food safety, will be brokered by ISAAA in Africa. Through the ISAAA *AfriCenter* located in Nairobi, Africa will have access to the worldwide network of experts in the scientific, regulatory and business fields that ISAAA has built.

COUNTRY SUPPORT

The earlier workshops of ISAAA have contributed in several ways to the development of regulations,

but country specific limitations may inhibit full implementation. Additional funding was therefore sought and found by ISAAA to assist South East Asian countries, such as Thailand, Malaysia and Indonesia, the Philippines and Vietnam and Latin American countries on an individual basis.

CONCLUSION

Building regulatory oversight is one of the challenges developing countries face in acquiring promising biotechnology applications to increase agricultural production in a sustainable way. A number of countries have faced this challenge and have succeeded in building a model that suits their needs and resources.

The International Service for the Acquisition of Agri-Biotech Applications assists in this development through workshops and individual country support, but implementation of the regulations is most enhanced by technology transfer projects.

The rapid development of biosafety guidelines in countries in the south creates opportunities for countries starting in this area to benefit from a vast range of experiences.

Through collaborative technology transfer projects between the north and the south, but increasingly also in south-south collaborations, ISAAA is in a strategic position to facilitate the sharing of the existing experience in regulatory oversight, thus enabling efficient development and implementation of regulatory oversight mechanisms for environmentally safe use of biotechnology applications.

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