

## ROLE OF INSTITUTIONAL BIOSAFETY COMMITTEES IN KENYA

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### ABSTRACT

In Kenya, like in many developing countries, the developments in biotechnology are ahead of formulation and implementation of national and institutional biosafety guidelines. Many institutions are involved in recombinant DNA technology using organisms and systems that require handling under stringent biosafety conditions but because of absence of such guidelines, compromises could easily be made. The consensus in Kenya is that both national and institutional biosafety guidelines should be established to enhance agricultural development through the safe use of biotechnology. This has been spearheaded by the Kenya Agricultural Research Institute which has formulated guidelines, adapting ideas from other institutions that are in line with Kenya's unique requirements in biotechnology.

**Key Words:** Biosafety guidelines, biotechnology, Kenya, rDNA

### RÉSUMÉ

Au Kenya, comme dans beaucoup de pays en voie de développement, les développements en biotechnologie sont en avance sur la formulation et l'exécution de lignes directrices nationales et institutionnelles de biosécurité. Beaucoup d'institutions sont concernées dans la technologie de recombinant DNA employant des organismes et des systèmes qui nécessitent d'être maniés dans des conditions de biosécurité rigoureuses, mais à cause de l'absence de telles lignes directrices, des compromis sont facilement acceptés. Le consensus au Kenya stipule que les lignes directrices tant nationales qu'institutionnelles devraient être mises au point pour améliorer le développement agricole par l'emploi de la biotechnologie. Cette tâche a été menée par l'Institut Kenyan de Recherches Agricoles qui a formulé des lignes directrices en adoptant les idées d'autres institutions, qui sont en accord avec les besoins uniques du Kenya en biotechnologie.

**Mots Clés:** Directives de biosécurité, biotechnologie, Kenya, rDNA

### INTRODUCTION

Many public research institutions and a few private companies in Kenya are engaged in agricultural research incorporating biotechnological applications. The Kenya Agricultural Research Institute (KARI), is Kenya's largest agricultural research institute. It is involved in agricultural research for generation and transfer of

technological packages in support of national food production and agricultural exports.

Kenya Agricultural Research Institute has incorporated biotechnology in its research programmes with the conviction that it will have a direct impact on its research and contribute to enhanced agricultural development. Based on the need to ensure that the products of biotechnology have no adverse effects to man and the

environment, the Institute has, in accordance with international standards, formulated institutional guidelines for its plants and livestock research.

### **STATUS OF BIOTECHNOLOGY APPLICATION AT KARI**

KARI has taken a lead among the National Agricultural Research Institutions (NARIs), in Kenya in planning and implementing agricultural biotechnology programmes encompassing both plant and animal health. At present, KARI is directly involved in the application of tissue culture micropropagation of pyrethrum, ornamentals, potatoes, strawberry and bananas. The Institute has extended its activities in tissue culture into collaborative research with both parastatal organisations and private sector firms in the country. Expansion of the Institute's research in tissue culture is planned to include major crops that are amenable to the technology (KARI, 1995).

KARI's research in the application of genetic manipulation and recombinant DNA technology is at present only limited to animal health. This consists of the development of hybridoma and DNA-based animal disease diagnostic tests and recombinant vaccines against various livestock diseases. In contrast, the application of genetic engineering in plant research is still limited, the only development at present being a collaborative undertaking with Monsanto for sweetpotato transformation against feathery mottle virus. Efforts are being directed into the establishment of research contracts with advanced institutions to enhance the use of productive biotechnology. These efforts are expected to lead to the development of genetically modified organisms (GMOs) which will be tested within KARI under suitable containment and be eventually released for use in the country.

Until recently, biosafety issues in KARI have been guided by the principles of good laboratory procedures and the existing national regulations and legislations governing and controlling the importation and movement of plant and animal biological materials. Phytosanitary regulations which provide for eradication and prevention of introduction of pests and diseases have been employed in the Institute's work. With the

incorporation and use of biotechnologies of recombinant-DNA for modification of genomes of plants and micro-organisms, the Institute has recognised the need to put in place relevant institutional biosafety guidelines to ensure safe practices and development of products of biotechnology (KARI, 1994).

### **INSTITUTIONAL BIOSAFETY STRUCTURE**

Research is commonly regarded as a single process in the context of biosafety. In practice, however, work leading to the release of GMOs can be divided into three phases: laboratory development, experimental release for field testing, and commercialisation. Each of these phases assumes different but overlapping objectives, practices and safety concerns and can, therefore, be addressed by different authorities. KARI's guidelines are essentially institutional, being intended to protect the health of the Institute's employees and the environment. They amount to laboratory containment categories based on the level of the hazard posed by exposure of workers to different organisms and experiments. The guidelines allow for the establishment of an institutional biosafety committee which will serve to self-regulate the low risk categories.

The Institute has not formulated or incorporated elaborate guidelines on experimental release as these are expected to be covered under national biosafety guidelines when these eventually come to being. In addition, KARI has not addressed guidelines relating to the commercial release of the products of biotechnology.

In formulating and implementing institutional biosafety guidelines, the Director of KARI appointed a KARI Advisory Committee on Biosafety (KACB) whose membership includes representatives from the Ministry of Health, International Laboratory for Research on Animal Diseases, the Department of Veterinary Services, the Departments of Agriculture and Animal Health within the local Universities as well as Crop and Animal Health Divisions of KARI. One of the committee members from KARI is the Biosafety Officer.

The major functions of the KACB are to advise

the Director and KARI's management on the formulation and implementation of institutional guidelines for research and development of GMOs, certifying the security of the facilities used for recombinant-DNA work according to the category of risk, approving proposals from the institute for work of the lowest category of risk, and forwarding to the national biosafety committee for review any proposals where the KACB is uncertain of the risk or where the genetic constraint is one of perceptibly high risk. The KACB also plays roles of ensuring that advice from the national biosafety committee is followed, develops training on biosafety issues for all KARI staff involved in research work with GMOs, and conducts regular review of containment measures and facilities. It establishes procedures for recording and filing individual biotechnological research projects in KARI, investigates and reports promptly to the Director of KARI all accidents, unexplained absences and illnesses.

In carrying out this work, the director appointed a Biosafety Officer (BSO) who is a member of the KACB. The BSO reports to the Committee on the Institute's biosafety issues relating to research with GMOs. The BSO also ensures through periodic inspections that laboratory standards are rigorously followed, supervises KARI's biosafety facilities and the application of the guidelines, provides advice on laboratory security, reports to the KACB and to KARI all significant research related accidents and illnesses, evaluation and monitoring of experimental protocols and provides technical advice to the principal investigators and the KACB on research safety procedures.

### OUTLINE OF INSTITUTIONAL GUIDELINES

The KARI biosafety guidelines formulation has taken into account ideas from other research institutions such as the International Potato Centre (CIP) and the Inter-American Institute for Cooperation on Agriculture. The guidelines were, however, developed with recognition of Kenya's unique requirements in biotechnology. They were, in addition, subjected to a critique by the international scientific community before finalisation.

In general, the guidelines cover areas of research and development involving all organisms and micro-organisms that are likely to occur in Kenya (Thitai, 1995). They incorporate establishment of the institutional biosafety committee through which they will be implemented, and describe containment facilities and biosafety practices for the different biosafety levels. In addition, they address recombinant - DNA safety combinations to be observed when dealing with GMOs during large scale production, when used in vaccine development and when using GMOs in the environment.

The guidelines define in detail, four levels of physical containment and the associated laboratory practices, containment equipment and special laboratory design required at each level. They provide a categorisation of micro-organisms on the basis of their levels of risk, outlining the general scientific considerations needed for risk assessment of micro-organisms in terms of characteristics of donor and recipient organisms and of the modified organism including gene expression and properties. The guidelines also deal with the containment and practice required for different categories of work with GMOs and local and exotic biological agents of plant and animal nature.

A small section of the guidelines deals with planned release and assessment of work involving the use of live organisms outside containment facilities. It is made clear that proposals for release be made to the national biosafety committee indicating objectives of the project, nature of the organisms and the genetic material and control of the released organisms.

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