

EXISTING BIOSAFETY REGULATIONS IN KENYA

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ABSTRACT

With biotechnology research and development activities rapidly expanding in Kenya, the country recognises the need for national biosafety guidelines and regulations. Existing laws that govern general safety in agriculture and public health and welfare do not deal directly with biotechnology. The National Council for Science and Technology is therefore in the process of formulating national biosafety guidelines. The guidelines are intended to cover genetically engineered animals, plants and micro-organisms; testing, production and release of genetically modified organisms (GMOs); and risk assessment and safety measures.

Key Words: Biosafety guidelines, biotechnology, GMOs, risk assessment

RÉSUMÉ

Avec le développement rapide des activités de recherche et développement en biotechnologie au Kenya, le pays reconnaît le besoin d'avoir de lignes directrices et de règlements sur la biosécurité nationale. Les lois actuelles régissant la sécurité générale en agriculture et en santé publique et le bien-être ne traitent pas directement de la biotechnologie. Le Conseil National de la Science et de la Technologie est, par conséquent, en train de formuler des lignes directrices sur la biosécurité. Les lignes directrices projetées vont inclure les animaux manipulés génétiquement, les plantes et microorganismes, l'expérimentation, la production et diffusion de GMOs ainsi que l'évaluation de risques et les mesures de sécurité.

Mots Clés: Directives de biosécurité, biotechnologie, GMOs, évaluation de risques

INTRODUCTION

Development in both traditional and modern biotechnology have made it possible to produce new products which were hitherto unknown. This has been quite obvious in cases where recombinant DNA (rDNA) is used in molecular genetics to produce transgenic animals and plants. This technology has been in existence since early 1970s when scientists discovered that rDNA could be used to "create" new organisms. This being one

of the new frontiers of science, it became one of the challenges to the theories of evolution and as a result it created fears among the public and raised matters of ethics. The debate regarding the possibilities of producing dangerous organisms through the use of biotechnology and releasing them to the environment still continues on, even though rDNA technology has now been in existence for several decades. Early scientists responded to the criticisms from the public by calling the Aislover Conference in 1974. At the

same time, there was a general moratorium on experiments using rDNA. Later, precautionary measures were suggested and these culminated in the production of biosafety guidelines at a national level. Such guidelines were expected to cover not only laboratory experiments but also field releases on both small and large scales.

Currently, several countries have produced national regulations and guidelines to govern research and development of products of genetic engineering. These regulations, where they exist, have varying degrees of strictness and are not uniform. As a result, a need to harmonise these regulations for countries in the same region has emerged. Some countries, for instance those of the European Union have issued directives for all member countries to follow when dealing with the contained use and deliberate release into the environment of genetically modified organisms. The Organisation for Economic Cooperation and Development (OECD) has also prepared documents which form the basis for national biosafety guidelines among its member countries (Zannoni, 1995). Other efforts at the international level include the Voluntary International Code of Conduct which has been prepared by UNIDO on behalf of the working group of experts from UNIDO/UNEP/WHO and FAO. There are also the Technical Guidelines for Safety in Biotechnology which have been prepared through the initiatives of the Departments of the Environment of the United Kingdom and the Netherlands following a workshop with participants drawn from many countries, including the developing ones.

Efforts are also being made by the parties to the Convention on Biological Diversity to come up with a needs assessment on an international protocol in biosafety. This is in line with Agenda 21 recommendations which were recently emphasised by the First Conference of Parties to the Convention on Biological Diversity regarding the need for the safe transfer, handling and use of living modified organisms resulting from biotechnology, in order to avoid adverse effects on the conservation of biological diversity and the sustainable use of its components.

EXISTING BIOSAFETY REGULATIONS/ACTS IN KENYA

There are several acts and regulations in place that deal with safety aspects (Wafula, 1995a, b). These include the following which are laws of Kenya:

| Agriculture: | Chapter |
|---|----------------|
| Seeds and Plant Varieties Act | 326 |
| Crop Production and Livestock Act | 321 |
| Plant Protection Act | 324 |
| Agricultural Produce (Export) Act | 319 |
| Agriculture Act | 318 |
| | |
| Public Health and Welfare: | |
| Food, Drugs and Chemical Substances Act | 254 |
| Dangerous Drugs Act | 244 |
| Public Health Act | 242 |
| Radiation Protection Act | 243 |
| Use of Poisonous Substances Act | 247 |
| Narcotic Drugs Act | 245 |

The above acts deal with general aspects of safety but do not deal specifically with genetic engineering involving rDNA. It has, therefore, become very necessary that guidelines which deal with biosafety in biotechnology in Kenya be formulated. The National Council for Science and Technology has embarked on this task.

Objectives. The objectives of the national biosafety guidelines will be to: (i) ensure public and environmental safety, particularly in accident prevention, containment and waste disposal when GMOs are utilized in research development as well as industrial processes; (ii) determine the measures for risk assessment, evaluation and risk reduction in all operations involving GMOs or any other processes of biotechnology including, but not limited to the, prescription of appropriate conditions for use of biotechnology and its products; and (iii) promote opportunities for the application and exploitation of innovative biotechnology products for the general well being of humanity.

Scope. The guidelines shall cover genetically engineered micro-organisms; genetically

engineered plants and animals; large scale production; deliberate or accidental release of micro-organisms, plants, animals and products derived from rDNA technology; and appropriate measures to avoid adverse effects in human health and the environment which might arise from the deliberate or accidental release and application of GMOs. For planned introduction of rDNA organisms into the environment, the guidelines will prescribe a criteria for assessment of the ecological aspects on a case by case basis .

ELEMENTS OF THE BIOSAFETY GUIDELINES

The biosafety guidelines will contain among others the following elements:

Risk assessment. This is a process of gathering diverse data to identify possible risks in research and development involving the use of rDNA. Risk assessment takes into consideration the properties of the organism and the environment into which it may be introduced. It also takes into account the possibility of containing and controlling the organism. Risk assessment can be carried out through hazard assessment, which involves identifying how an organism might be harmful, or through exposure assessment, which involves estimating the amount of organism to which the environment, people or other organisms might be exposed.

Risk management. Risk management is a process of reviewing alternatives from the results of risk assessment and selecting the best regulatory action. For management purposes it is important that the organisms involved and the method used in application is taken into consideration. One management method which has a direct bearing on the degree of risk and therefore needs to be considered at every stage, is the type and level of containment. Two types of containment will be considered, namely, biological and physical containment.

Familiarity. Familiarity is a technique which allows decision makers to arrive at decisions which are based on past experiences gained as a result of introducing organisms into the

environment. It relies heavily on field tests and cumulative data obtained from laboratories and other facilities. Eventually the entire class or group of introductions may become familiar enough to require minimal oversight. When familiarity has been satisfied such that there is a reasonable assurance that the organism and other introductions are similar to known introductions, and when these have been proved to present negligible risk, then the introduction is assumed to be suitable for field testing according to established practice.

The guidelines will focus on plants, animals and micro-organisms which are genetically engineered or modified for use in environment, industry, agriculture and human health. The guidelines are expected to cover the following areas: field releases; public education and awareness; ethical implications and legal issues; institutional linkages and international cooperation; establishment of a Biosafety Committee; and liabilities and compensation.

IMPLEMENTATION

The drafting of the national biosafety guidelines involves many actors who are users of the technology and the products derived from that technology. It is therefore envisaged that technical papers which will form the working documents needed to support the guidelines, will be prepared by experts drawn from the various disciplines and professions. The national guidelines will clearly show the institutional linkages with those institutions which are involved with rDNA work. This is especially important because it is expected that such institutions will develop their own institutional biosafety guidelines. The Kenya Agricultural Research Institute has already developed its own guidelines (Wafula, 1995b).

TARGET

Research and development in Kenya is carried out by international organisations and the public sector. This research has, in some cases, involved the use of rDNA. This therefore means that biosafety guidelines would be very useful to many organisations within the country which are involved in research and development activities

using rDNA. Some of these organisations may also carry out collaborative activities with other countries and international organisations. As a result the government is keen to see that there is safe use of biotechnology products and that the research carried out by various organisations and individual does not pose a risk. As a result, the National Council for Science and Technology (NCST) is taking a leading role in coordinating the preparation of the national biosafety guidelines which, when completed, will be disseminated to private and public institutions including research institutions, industry and various relevant international organisations.

CONSTRAINTS

Preparation of the biosafety guidelines requires that a wide cross section of people be involved in the discussions. The NCST would like to hold two workshops for experts to debate the issues which

will be in the draft guidelines. This calls for funding for such workshops, and at the moment efforts are being made to find a financing organisation. It is pertinent to state that the implementation of the national guidelines will require international support and collaboration in the realisation of its objectives.

REFERENCES

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