

BIOSAFETY REGULATIONS IN SOUTH AFRICA

E. J. MORRIS

Research and Development Department, AECI Limited
Private Bag X2, Modderfontein 1645, South Africa

ABSTRACT

South Africa has an active national biosafety advisory committee known as SAGENE (the South African Committee for Genetic Experimentation). The activities of SAGENE are backed by various pieces of legislation. New comprehensive legislation is currently being drafted by an inter-departmental government working group, with the active participation of SAGENE, which will promote the responsible development, production, use and application of genetically modified organisms (GMOs). In terms of the legislation, a new committee will be formed which will be considerably strengthened and will have the power to make binding decisions.

Key Words: SAGENE, legislation, genetically modified organisms,

RÉSUMÉ

L'Afrique du Sud dispose d'un comité national de biosécurité connu sous le nom de SAGENE (le comité sud Africain d'expérimentation génétique). Les activités de SAGENE sont soutenues par différents articles de la législation. Une nouvelle législation plus complète est en train d'être rédigée par un groupe interdépartemental du gouvernement, avec la participation active du SAGENE qui va promouvoir le développement, la production, l'usage et l'application responsables des organismes génétiquement modifiés (GMOs). Les termes de référence de la législation stipule qu'un nouveau comité sera créé et renforcé considérablement afin de pouvoir prendre des décisions à caractère légal.

Mots Clés: SAGENE, législation, organismes génétiquement modifiés

INTRODUCTION

In South Africa, biotechnology research takes place in a number of universities, government research institutions and industries. The technologies employed range from traditional microbial fermentation to sophisticated genetic manipulation techniques.

Traditional fermentation technology is widely practised in South Africa in breweries and the dairy industry, in the production of bakers' yeast,

in production of human and animal vaccines, and in other areas. Various large South African companies have recognised the potential for biotechnology and are investing heavily in it. For example, a large world-class plant to manufacture the amino acid lysine by a microbial fermentation process is currently under construction. Plans for production of citric acid, penicillin and biopesticides are also well advanced.

Modern biotechnology, and more specifically recombinant DNA (rDNA) technology, was

introduced into South Africa during the 1970s, when the technology was still in its infancy. At that stage, it was primarily practiced in South African universities, as well as in some government research institutes. Since that time, more advanced biotechnological techniques have started to become routine at the research level, and a number of organisations have developed products using these techniques which they hope to commercialise in the near future. These include genetically engineered micro-organisms and plants.

Agricultural biotechnology has an important role to play in the country's development. Agriculturally, the country is largely self-sufficient. Over 80% of the land is used for agriculture and forestry, although a large proportion of this is natural veld which is used for stock grazing. Around 14 million hectares are under cultivation for crop production. Traditional agriculture and plant breeding are supplemented by the use of tissue culture techniques and, more recently, the development of plants improved through the application of biotechnology. Tissue culture and seed companies have recognised the potential of biotechnology to contribute to their businesses through genetic fingerprinting, disease indexing, and the development of improved plants using techniques such as embryo rescue, protoplast fusion, mutation and genetic engineering.

THE CREATION OF SAGENE

Scientists working with the new genetic engineering technologies in the late 1970s felt the need, at that stage, for some organisation that would act as a central focus for consideration of the issues that such technology brought to the fore. Accordingly, in 1978, the organisation known as the South African Committee for Genetic Experimentation (SAGENE) was created. It operated under the aegis of the Council for Scientific and Industrial Research (CSIR) and was specifically concerned with laboratory containment of rDNA experiments, approval of projects, training courses and laboratory standards.

As the technology became more familiar at the laboratory level, SAGENE played a less prominent role, and the organisation became somewhat dormant. However, around 1989 it

was recognised that there was a need for an organisation to take responsibility for the environmental release of genetically modified organisms (GMOs). Field trials were in place overseas, and South Africa meanwhile had no organisation through which any request for release of GMOs could be channelled. Consequently, a decision was taken to widen the mandate of SAGENE to include the release into the environment of GMOs. SAGENE was, therefore, officially reconstituted in terms of an announcement in the South African Government Gazette (Anonymous, 1994). The Foundation for Research Development (FRD) provides the Secretariat for SAGENE.

Terms of reference. SAGENE's terms of reference are as follows: SAGENE will (i) act as the national advisory body on the genetic modification of organisms and serve the interests of the scientific community and the public in this regard; (ii) liaise, through the FRD, with the relevant international groups and/or organisations concerned with biotechnology; (iii) advise, on request or *mero motu*, any person and/or body concerned with research into or on the genetic modification of organisms, with regard to guidelines for the application, as well as the possible effects on the environment of the release of GMOs; (iv) advise on request or *mero motu*, any minister, statutory or government body, industry, or any other body or person, on any form of legislation or controls pertaining to the importation and/or release, into the environment of GMOs.

The SAGENE committee consists of: (i) a Chairperson, who is appointed for a three year term on agreement between the Agricultural Research Council, the CSIR, the FRD and the Medical Research Council; (ii) a representative appointed by the Department of National Health and Population Development; (iii) a representative appointed by the Department of Environment Affairs; (iv) a representative of the South African universities; (v) a legal representative who will represent the interests of the public in general; (vi) a representative from the non-government sector who will represent the ecological community; and (vii) a representative of the

business community/industry. Should sufficient expertise to deal with any matter not be available from within the SAGENE committee, a sub-committee that may include any other experts as deemed necessary will be convened.

In terms of SAGENE's remit, a GMO is defined as an organism whose genes, or genetic material, have been modified in a way that does not occur naturally by mating or natural recombination or both. This includes rDNA technology and similar techniques, as well as cell fusion or hybridisation techniques by methods which do not occur naturally. Processes which can occur naturally such as mutation are excluded at this stage. The committee's remit includes transgenic microorganisms, plants and animals. However, it does not currently deal with human gene therapy, as the National Co-ordinating Committee for Genetic Services of the Department of National Health and Population Development is more properly qualified to deal with this issue and has agreed to assume responsibility.

Activities of the SAGENE committee. In the recent past, SAGENE has drawn up various sets of guidelines covering the use of GMOs both in the laboratory, in large scale production, and for environmental release. A Questionnaire and Procedures document is supplied to anyone wishing to release a GMO in South Africa, and favourable feedback on these documents has been obtained from various sources.

Any individual or company wishing to import plant material must do so through the Directorate of Plant and Quality Control of the Department of Agriculture. Any application for importation of genetically modified plants is referred to SAGENE for comment.

A number of field trials have been approved by the SAGENE committee. These include trials on genetically engineered cotton, maize, lucerne and canola (rape), all of which were developed overseas. A number of overseas companies have shown interest in testing their plants in the South African climate, and in using the Southern Hemisphere counter-season to bulk up seed more quickly than is possible by growing only in the Northern Hemisphere. Recently, a field trial on genetically engineered strawberries that were

developed by South African scientists has also been successfully carried out after approval was sought from SAGENE.

STRENGTHS AND WEAKNESSES OF BIOSAFETY IN SOUTH AFRICA

Through the activities of SAGENE, South Africa has in place an effective, pro-active advisory committee on biosafety. A single centralised committee of this type that can act as the focus for all issues relating to novel organisms has advantages in its simplicity and transparency to industry and the public. Many of the committee members are themselves actively involved in biotechnology research, and are, therefore, competent to advise on the application of the technology. Various interest groups are also represented to ensure that the committee has credibility in the community.

The FRD is committed to providing limited funding for the expenses of committee members. Various government departments also actively support and encourage the activities of SAGENE.

Nevertheless, the current situation has some inherent weaknesses, which are actively being addressed. As an advisory body, SAGENE relies on the final authorisation to release a GMO being granted by an appropriate government department. SAGENE is not in a position to employ any inspectors, and, therefore, also relies on the relevant government department to inspect any release that may take place. Experience has shown that, in terms of existing legislation, the government departments are not always in a position to take action. It is thus recognised that legislation relating to the use and release of GMOs needs to be strengthened. Activities in this regard are already under way (see below). Additional finances will also need to be made available so that independent studies can be commissioned as required, and so that the expenses of the committee members (who all serve on a voluntary basis) can be more adequately covered for. This could be done in part through the levy of a fee to applicants.

The potential for lack of confidentiality and conflict of interest has been raised as a perceived problem by certain parties who are concerned because the members of the SAGENE committee

are themselves active in biotechnology development. However, all members of the SAGENE committee and any *ad hoc* subcommittee sign a deed of confidentiality by which they guarantee not to divulge any information which is designated as commercial-in-confidence. In addition, an applicant may specify that a particular committee member should be excluded from the review process if any potential conflict of interest might arise.

LEGISLATION RELATING TO GMOs

A number of activities relating to GMOs are already controlled in terms of existing legislation. For example, importation of genetically modified plants is covered by means of the Agricultural Pests Act which was amended in 1991 specifically to include GMOs. The Occupational Health and Safety Act will include regulations on hazardous biological substances. These regulations, which are still in the draft stage, specifically mention GMOs and their release. In addition, the Integrated Environment Management Procedure, which forms part of the Environment Conservation Act, also specifically mentions GMOs and their release. Finally, the Foodstuffs, Cosmetics and Disinfectants Act covers all foods, including those produced by applied technology.

In light of the recognised need for additional integrated legislation that applies specifically to GMOs, a government inter-departmental Working Group for Legislation on GMOs has been convened. SAGENE members form an active part of the Working Group. This group is currently in the process of drafting legislation by means of which a new statutory committee with executive powers will be formed. This committee will have a permanent secretariat based within the responsible government department. The new committee will act as the Competent Authority in all matters concerning the use and release of GMOs, and will interface with other relevant government departments (e.g. Agriculture, Health, etc.). The committee will consist of two nominees from each of the interested government departments, as well as four nominees from outside government. It is intended that at least half of the nominees should be technical experts specialising in genetic manipulation. In addition, the committee

will be able to form sub-committees incorporating other areas of expertise. The new legislation will deal specifically with the development, production, use and application of GMOs including applications of human gene therapy, but must take into account and harmonise with all existing relevant legislation.

During the interim period, before the new legislation is promulgated, it is recognised that there may be instances in which the existing legislation is inadequate to deal with certain work with GMOs. For this reason a Code of Conduct has been drawn up, and is to be distributed, along with SAGENE's guidelines, to all organisations known to be involved in genetic manipulation work (Anon., 1994).

Harmonisation of regulations. The South African legislation is being drawn up with reference to that of other countries, paying particular regard to the European Union directives and the existing UK legislation. However, the legislation also recognises the potential of GMOs to provide enhanced quality of product, expansion of employment opportunities and products and services previously unforeseen. The act is, therefore, intended to ensure prompt, efficient, ethical and safe deployment of biotechnology throughout South Africa.

As exotic and novel organisms may well stray beyond national boundaries, the draft legislation also refers to the need to foster relationships with any neighbouring national or regional biosafety organisations with the aim of developing complementary and comparable policies.

In keeping with these aims, members of the SAGENE committee are developing relationships with others involved in biosafety both in the African region and around the world. Membership of the newly-formed African Regional Standing Committee on Biosafety is seen as a key element in this process.

The FRD has agreed to act as a node for the BINAS databases which are administered by UNIDO. These databases cover useful information on releases and risk assessments relating to GMOs, and will be of value in helping South African scientists and others involved in biosafety to learn from the experiences of biosafety organisations around the world.

CONCLUSION

In South Africa, as in many other countries, the ways in which novel organisms produced through the application of biotechnology are being handled continually undergo modification as more experience is gained. The presence of an active advisory body (SAGENE) with existing expertise

has laid a sound foundation upon which to build for the future.

REFERENCE

Anonymous. 1994. South African Government Gazette No. 15420. 14th January, 1994, pp. 17-18.

