

## Biosafety Activities in the Southern and Eastern African Community (SEAC)

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### Abstract

Biotechnology and Biosafety activities in Africa have taken the form of training workshops, symposia and scientific meetings in biotechnology and biosafety. Such activities were sponsored by the UN Agencies, such as UNEP, UNIDO, UNESCO, UNDP and their subsidiaries such as, ICSU, IUUBS, ABN and also by the donor community (Rockefeller Foundation, GTZ, DGIS, SAGENE, COGENE, CIDA, SIDA, DANIDA, CSC, ODA, etc.).

Need for cooperation in safety in biotechnology was initiated as a follow-up of the UNCED Agenda 21. An African Regional Conference for International Cooperation on Safety in Biotechnology was held 11-14th October 1993 in Harare, Zimbabwe. The conference aim was to contribute to international cooperation in Biosafety, with specific attention to the initiation of biosafety programs, their implementation at National subregional, regional and international levels. The conference recommendations resulted in the establishment of National Biosafety Committees, Subregional and Regional Coordinating Biosafety Committees, National Biosafety Focal Points and Regional Biosafety Focal Point. Each National Biosafety Committee was given the task to draft biosafety guidelines/regulations. A Regional Biosafety Focal point for Southern and Eastern African Countries (13 SEAC), was established in 1993 and was housed at the SIRDC, Harare, Zimbabwe. The RBFP has carried out a number of activities since its establishment such as organizing and hosting A Workshop of the Regional Standing Committee on Biosafety, Harare 29 - 30th May, 1995, coordinating the establishment of a Biosafety Network Newsletter, collaborating in the establishment of the Zimbabwe Biotechnology Advisory Committee (ZIMBAC), establishment of a ZIMBAC Newsletter, planning and participating in a Regional Seminar on Planning and Formulation of Policies for Agricultural Biotechnology: Turning Priorities into Feasible Programmes, April 23-27, 1995, National Workshop on Priorities for Biotechnology in Livestock Improvement, Harare 5 - 7 June, 1995.

For future direction, we need to put together effective mechanisms on biosafety evaluation of GMP, impact assessment, risk assessment, risk management. Many of the countries in our region have been approached by multinational organizations to test GMOs, but there are no effective mechanisms to make effective decisions as there are no experts on release issues including contained release of GMOs.

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## Biosafety

Biosafety may be defined as: The existence of effective mechanisms for the safeguard of public health, safe agricultural production, safe industrial production; safeguard of natural plant species and of the environment, from negative consequences of the practice and applications of biotechnology and its products: This may be achieved through proper risk assessment and risk management, testing of GMOs, contained release of GMOs and controlled release of GMOs. Safety in biotechnology requires the expert knowledge in approaches, practices and applications of biotechnology ; without sacrifice of plant and human health; without loss to biodiversity and with the maintenance of a friendly and safe environment.

The majority of the countries in the SEAC have not yet embarked on the formulation, development and implementation of biosafety guidelines or regulations. This shortcoming is mainly due to the lack of resources to develop the necessary expertise for the assessment of potential risks posed by the application of biotechnology. There is a general lack of awareness at the national level on the importance of biotechnology and related issues and needs for biosafety. There is also a lack of clear government policy on biotechnology. In addition, there is a serious lack of governmental budget support initiatives in biotechnology. More importantly, there is no program for training in biosafety issues. The University of Zimbabwe (UZ) has an Msc Degree program in biotechnology, but there is no course in that program on biosafety, impact assessment, risk assessment and risk management issues. The economies of the SEAC are declining on a sliding scale, and cannot sustain long-term investments in biotechnology and biosafety R & D. There is lack of indigenous industrial growth. Nevertheless a number of activities have taken place at national level in a number of countries in the region. In Zimbabwe, the Research Council of Zimbabwe has developed draft regulations which cover; recombinant-DNA technology research with microorganisms and their use in large-scale industrial development, genetic transformation of plants and animals (GMOs), deliberate or accidental release of GMOs to the environment. The Biosafety guidelines/regulations have gone through a Cabinet Committee and through a Parliamentary Committee. Zimbabwe is one of the few African countries which will shortly have an internationally accepted legislation on biosafety. The Research Council of Zimbabwe adopted the recommendation of ISNAR to establish.

- 1 . **The National Biosafety Board**, which sets policies and procedures at the national level and provides technical advice to regulatory authorities and institutions.
- 2 . **The Institutional Biosafety Committees**, at institutions carrying out biotechnology research, such as the Biotechnology Research Institute (BRI), the University of Zimbabwe, National University of Science and Technology, the Tobacco Research Board (TRB), Cotton Research Institute (CRI) Horticultural Research Institute, Department of Research and Specialist Services, etc. (Chigogora, 1995).

### 3. The Zimbabwe Biotechnology Advisory Committee (ZIMBAC)

In South Africa there is a national biosafety advisory committee: South African Committee For Genetic Experimentation (SAGENE). The activities of SAGENE are backed by legislation. SAGENE promotes responsible development, production, and application of genetically modified organisms (GMOs), drafting of guidelines covering use of GMOs, in the laboratory and in large-scale production. South Africa has made a number of releases of GMOs (Table 1). Other nations in the region are at various stages of developmental activities in safety on biotechnology (Southern and Ferreira, 1993).

### Cooperation in safety biotechnology

Cooperation in Safety in Biotechnology must take place at the subregional, regional level, and the international level. The developing countries must cooperate with the developed countries, who have the resources and the technical know-how. Cooperation in safety in biotechnology must first be implemented at a sub-regional level, such as South→South- Level. African countries must cooperate in problems which are common to the region. There is also need to cooperate at regional level, to solve more common problems to the region. The Southern and Eastern African Region is an example. Other subregions may be organized to achieve more sustainable cooperation in biosafety. The Southern and Eastern African subregion is composed of: Angola, Botswana, Lesotho, Malawi, Ethiopia, Kenya, Mauritius, Mozambique, Namibia, South Africa, Swaziland, Tanzania, Uganda, Zambia and Zimbabwe.

The objectives of the SEA are to: employ safe biotechnology practices in the promotion and achievement of sustainable growth, promotion of health for all, promotion of sustainable agricultural productivity, promotion of food security, prevention of poverty and hunger, and promotion and achievement of harmonization on regional safety in biotechnology. The areas of cooperation are: agricultural biosafety for food production and for food security; development of industrial base for job security, human resources, development in science and technology and capacity building.

### Efforts at cooperation in safety in biotechnology

**The African Regional Conference For International Cooperation On Safety In Biotechnology was held in Harare, Zimbabwe during the period 11 - 14 October, 1993 (Van der Meer *et al.*, 1993)**

The aim of the conference was to contribute to international cooperation in safety in biotechnology, with specific attention to national implementation, regional and international cooperation and harmonization of regulations on safety in biotechnology. Fifty conference participants came from Botswana, Kenya, Malawi, Mozambique, Namibia, South Africa, Swaziland, Tanzania, Uganda, Zambia and Zimbabwe as well as twenty international experts discussed how to ensure international cooperation in safe applica-

tion of biotechnology. The participants were involved in biosafety issues, either at the policy level (ministries, regulatory bodies), as researchers (universities, research institutes), or at the user's level (industry, consumers, farmers). The conference concluded that safety in biotechnology should be considered in the development and application of biotechnology in the countries of Southern and Eastern Africa, as a matter of urgency. The conference concluded that regional meetings can contribute to international cooperation and harmonization.

The participants resolved to urge the Governments of Southern and Eastern Africa to facilitate and give priority to biotechnology policies including safety mechanisms in each of the countries. Safety mechanisms should include guidelines and/or regulations, as well as biosafety committees at the national and institutional level, and should be adapted to specific national conditions. The conference also resolved that cooperation should be sought through appropriate regional coordinating organizations so as to share relevant expertise, and inform on criteria, procedures, and decisions on specific activities. In this context the conference recommended that a second meeting should be held within one year and that for this purpose a contact person should be identified for each country in the region.

The conference furthermore emphasized the importance of regional and international harmonization of safety in biotechnology through appropriate international instruments. The conference agreed and formulated ten recommendations and urged their implementation on an institutional, national, regional and international basis. Greater emphasis was placed at Regional Cooperation in the implementation of the recommendations.

The Conference agreed and recommended that each participating country should put in place guidelines or regulations, on safety in Biotechnology. Dr. S. Feresu's submission to the conference of guidelines on safety in biotechnology in Zimbabwe could be used as blueprint (Feresu, 1993).

## **Implementation of biosafety activities in southern and eastern African subregion**

### **1. Guidelines/Regulations**

Each member state was supposed to have :

- Formulated and implemented a national policy on biotechnology,
- Initiated the development of appropriate guidelines and/or regulations,

Established a coordinating body/biosafety committee to draft guidelines and/or regulations; and consulted interested parties, including the public and special interest groups; this should result in a working document from which national policy would be developed,

- Updated and revised existing legislation.

## 2. Biosafety committees

- Biosafety committees should have been set up at the institutional, national and regional levels as soon as possible,
- The biosafety committees should have outlined tasks and responsibilities to be specified in the guidelines and/or regulations,
- A regional coordination biosafety committee should have been established to assist national biosafety committees.

## 3. Risk assessment

Each member state should develop the capacity to :

Define potential risks and appropriate risk management procedures,

There should be an effort to develop and harmonize risk assessment mechanisms at the national, regional and international levels,

Each member state should provide training in risk management,

Establish biosafety committees to avoid conflicts of interests,

In specific cases *ad hoc* committees could be established, coordinated by relevant bodies, to assist in risk management,

International organizations (e.g. the Biotechnology Advisory Commission of Stockholm Environment Institute) should be asked to give assistance in building risk assessment and management capacity.

## 4. Data bases

For databases, the conference recommended that a regional coordinating body be established and keep track of existing databases, and through networking, prepare inventories and identify a home for information storage,

Institutional strengthening in information management.

## 5. Training

- A mechanism for the appropriate training of researchers, skilled scientists, biosafety officers and technicians by international experts should be developed,
- These appropriate training activities should be handled at national and regional levels, including a regional training institute.

## 6. Networking

The SEA was urged to develop an effective networking by:

- Organizing regular meetings of national biosafety committees at the regional and international levels,
- Establishment of newsletters, e-mail,
- Organization of a follow-up meeting of the Conference,
- Use of existing networks and development of new ones,
- There should also be an effort to encourage networking of national biosafety committees,

And to

- Promote scientific exchange through workshops, seminars and conferences, at national, subregional and regional levels.

## 7. Monitoring

A monitoring mechanism should be developed in order to:

- Review the function of existing control and
- Develop long-term monitoring and evaluation programs, funded through fees.

## 8. Public education

There is a strong need to develop:

- National and regional instruments and programs for public education through the sensitization of the media to educate the public,
- The National committee should disseminate information on biotechnology and biosafety to develop public interest at an early stage.

## 9. Funding

- Each member state should:
- Encourage the private sector to become involved in funding of biosafety,
- Each National Biosafety Committee should encourage governments to recognize the importance of funding of biosafety with reference to their commitment to

Agenda 21, and

- The network management mechanism should be used to approach funding agencies for funds to support national and regional activities in biosafety.

## 10. Harmonization

- There is a need to define the most appropriate international instruments for regional and international harmonization of biosafety guidelines and/or regulations, among others by communicating with relevant UN organizations and
- Establish a regional coordinating body to harmonize guidelines and/or regulations.

## Needs that have been met

The need for Regional Cooperation On Safety in Biotechnology, has largely been met through the establishment of the Regional Biosafety Focal Point, housed by the Scientific and Industrial Research and Development Centre (SIRDC), Harare, Zimbabwe.

A Regional Coordinating Committee, composed of one delegate from each participating country was established at the African Regional Conference for International Cooperation on Safety Biotechnology, October 11 - 14, 1993, Harare to constitute the Regional Biosafety Focal Point.

The SIRDC was commissioned by the Dutch Ministry of Development Cooperation to administer The Regional Focal Point Safety In Biotechnology. The SIRDC received a grant from DMDC.

A Project Officer has been appointed to handle the daily operations of the Regional Focal Point Secretariat. (The Project Officer is Mrs. Joy Chigogora, Regional Focal Point, P O Box 6640, Harare, Zimbabwe, Telephone 263-4-860 337, Fax 263-4-869 351) as follows :

1. To establish an office system that facilitates the management of a regional network on safety in biotechnology,
2. To develop an information system (newsletter, fax, bulletins, database information directory, etc.) that facilitates information storage, retrieval and dissemination,
3. To develop documentation briefs on the functions of the Focal Point and its planned program of activities during the operational year,
4. To undertake a working/familiarization trip to four of the 13 countries participating in the network so as to publicize the activities of the Focal Point and to consolidate the program of collaboration within the network,

5. To develop documentation on the status of safety-in-biotechnology provisions in each of the 11 countries belonging to the network. The country coordinators for biosafety will help gather information for this documentation,
6. To develop a library of books, documents, publications, specific-country guidelines and any other relevant literature to safety in biotechnology,
7. To undertake any other tasks the Director General of SIRDC may assign from time to time in order to enable the program of the Focal Point to achieve its objective.

### Activities of the regional biosafety focal point

The RBFP organized and hosted a workshop of the Regional Standing Committee on Biosafety in Harare on 29 - 30th May 1995. Participants in this workshop came from Botswana, Kenya, Malawi, Mozambique, Namibia, South Africa, Swaziland, Tanzania, Uganda, Zambia and Zimbabwe. The delegates gave country reports, which except for South Africa, Zimbabwe, Kenya and Uganda, reflected very little national activities in biotechnology and biosafety. Discussions at this workshop covered: establishment of National Biosafety Focal Points (NBFP), strengthening of the Regional Biosafety Focal Point, setting up of National Biosafety Committees (NBC), information dissemination on networking establishment of databases, center empowerment of NBFP and capacity building in human resources.

### Resolutions and recommendations for action

1. The delegates resolved to urge their respective governments to support and empower the National Biosafety Focal Points (NBFPs) with the responsibility for biosafety issues and to strengthen the Regional Biosafety Focal Point (RBFP),
2. The delegates also resolved to call upon their respective governments: to establish and support a National Biosafety Focal Point that will be responsible for the drafting of national biosafety guidelines or regulations for their countries,
3. To entrust the National Biosafety Focal Point with the responsibility of coordinating and implementing these guidelines in such a way that while agriculture, human health and the environment are safeguarded, commercialization of biotechnology products is also facilitated,
4. To entrust the National Biosafety Focal Point with the responsibility of promoting capacity in risk assessment and management and to support their activity by providing some funding for it.

### Workshop recommendations

The delegates at this workshop recommended that:



1. The National Biosafety Focal Points (NBFPs) put forward proposals for the support and strengthening of the Regional Biosafety Focal Point (NBFP) and the NBFPs themselves, which will be forwarded to the Special Programme of Biotechnology and Development Cooperation of the Directorate General for International Cooperation (DGIS) through the Zimbabwe Biotechnology Advisory Committee (ZIMBAC) for review and consideration,
2. Periodic regional training in risk assessment and management be organized by the RBFP and that all the information and results so obtained be disseminated in each participating country through the NBFP,
3. The RBFP assess the possibility of access to international biosafety database and the feasibility of disseminating relevant information to the NBFPs.

### Other activities

Since the workshop, the following activities have been undertaken by the RBFP.

- Establishment of the Biosafety Network Newsletter. The RBFP has collaborated in the establishment of the Zimbabwe Biotechnology Advisory Committee (ZIMBAC); and the establishment of the ZIMBAC Newsletter Biotechnology, a quarterly newsletter on Biotechnology in Agriculture and Industry.
- The RBFP has been an active participant in a Regional Seminar on Planning and Policies for Agricultural Biotechnology: Turning Priorities into Feasible Programmes, S.A. April 23-27, 1996 and in a National Workshop on Priorities for Biotechnology in Livestock Improvement (Harare, 5-7 June, 1995).

### Safety evaluation activities of genetically modified organisms

In most of the Southern African and Eastern African Countries very little research in biotechnology, except for Zimbabwe and South Africa, is being carried out. Where some biotechnology research is going on, like in Zimbabwe, the absence of universally accepted legislation on biosafety, has prevented any implementation of biosafety activities. The international and multinational companies which own the genes and the GMOs have prevented the testing of their GMOs in the countries where there are no guidelines. In the Southern region, only South Africa has internationally accepted guidelines. In Zimbabwe, Kenya and Uganda, some biosafety guidelines have been drafted and were submitted for consideration by the parliament. It is therefore clear that of all the 13 SEA countries which have adopted a biosafety cooperation protocol, only South Africa has biosafety guidelines and a National Biosafety Committee - "The South African Committee on Genetic Experimentation (SAGENE) Activities of SAGENE in 1995".

## Report on activities carried out by SAGENE in 1995

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1995 has been a busy year for the SAGENE committee. Formal SAGENE meetings were held in January and July, but activities proceeded throughout the year.

A significant number of applications for field trials of genetically modified plants were received, and details of the trials which were approved by SAGENE are given in the Table below. SAGENE advises the Department of Agriculture, which must then give the final permission for the trials to take place.

The SAGENE committee members have been actively involved during the year in the drafting of a new legislation on the use and release of GMOs. This activity is being coordinated through an inter-departmental Working Group, which involves all government departments with an interest in the subject. The legislation has already been through a number of drafts, but further changes will still be required before it is ready for publication. It is hoped that the legislation will be introduced during 1996.

In the *interim* period until the new legislation is introduced, the SAGENE committee has drawn up a Code of Conduct, which is being sent, along with SAGENE's guidelines, to all the organizations involved in GMOs. Signatories to the Code of Conduct will agree to consult SAGENE on the use and release of GMOs, and to abide by the recommending of the SAGENE committee.

SAGENE has also been involved in negotiations concerning the proposed Biodiversity Protocol, and Dr J. Hoffmann of the SAGENE committee has attended meetings in Cairo and Madrid to discuss this issue. The position of SAGENE is that it is more important at present to address the issues of capacity building in developing countries than to introduce a legally binding protocol at this stage. The International Technical Guidelines on Biosafety which are being developed through UNEP are an important instrument in this regard, and SAGENE would therefore support the finalisation and adoption of these guidelines as a matter of priority. SAGENE members have been involved in a number of regional meetings relevant to biosafety, and hope that the interaction with colleagues in other African countries will continue to grow productively.

## References

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**Table 1** Summary of Applications to SAGENE in 1995 for the Release of Genetically Engineered Organisms

Date	Crop	Trait	Gene	Selection	Purpose	Company
May 95	Soybean	Herbicide resistance	Roundup	Npt 11	Field trial	Camia
Jun 95	Strawberry	Herbicide resistance	glufosinate ammonia	Npt 11	Field trial	Infrultec
July 95	Cotton	Insect and herbicide resistance  Herbicide resistance	<i>B.t.</i> / bromoxynil  imidazolinone	Npt 11	Field trial Seed increase and breeding	Calgen
Aug 95	Cotton	Insect tolerance	<i>B.t.</i>	Npt 11	Seed	Delta and Pne Land
	Cotton	Herbicide tolerance	Roundup			
	Cotton	Insect and herbicide tolerance	<i>Bt</i> and Roundup			
Aug 95	Maize	Herbicide resistance  Insect resistance Insect and herbicide resistance	Roundup  <i>B.t.</i> <i>B.t.</i> and Roundup	Glyphosate	Field trial and breeding	Monsanto
Sept 95	Maize	Insect resistance	<i>B.t.</i>	Npt11 glyphosate	Field trial and breeding	PHI