Chapter 5

Biosafety Policy

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This chapter examines the role of biosafety and its intentions, and the opportunities and challenges that the Southern African Development Community (SADC) region is faced with in connection with research and development in genetic engineering (GE), the importation of GE products, and the movement of such products within and across various SADC countries. It also presents various positions open to the region to explore as it considers the use of biotechnology as one of the tools for agricultural development.

Southern African countries are at different levels of development, including the use of biotechnology. Some countries are receiving assistance from international agencies to develop frameworks for and undertake training in the use of this technology. Recently a number of countries in the region accepted genetically modified (GM) food aid, in most cases before biosafety policies and frameworks were in place. Given the high degree of transboundary movement of goods and people in the region, it is important that decisions by individual countries be open for consideration by neighbors. Further, multinational companies have long been seeking opportunities to introduce biotechnology to develop food and seed industries. A common position is therefore called for to form a basis for biosafety regimes in the interest of food, agriculture, and natural resources for which the SADC already has a policy organ. The success of a biosafety policy framework will depend on country and regional commitment and cooperation, enabling policy instruments, sustainable human and financial support, and enhanced public understanding and awareness of biosafety issues. As a regional group with a development focus based on integration, the SADC is well poised to provide leadership for and guidance to national efforts to develop and enact biosafety policy frameworks.

The Basis for Regulatory Measures in the Life Sciences

Most health problems of humans and animals arise from their close association with the environment, which individuals cannot control but can influence to the detriment of the rest of the population. Human-initiated changes therefore need to be checked to ensure that key public goods continue to be enjoyed without exclusion. The domains of food, human and animal health, and environmental integrity, without reference to biotechnology products, are safeguarded through regulatory measures and policies designed in the public interest. Laws and regulations are developed governing public health, pest control, food and drugs, hazardous substances, agricultural practices, and environmental conservation. Often the aim is to check the exploitative nature of industry and other commercial activities, particularly given the growing need to earn income from new products. Policy, regulatory, and legislative provisions curb private excesses in the interest of society. Such provisions assure consumers and other groups that goods and services produced outside their control will meet certain quality guarantees for their health and welfare. Private businesses that comply may benefit from expanded sales due to enhanced trust.

Potential Risks

Set against the potential benefits biotechnology offers are potential risks. For instance, new organisms could crowd out other organisms, thereby changing ecosystems because of their improved vigor in the environment. GE may alter the internal chemistry of an organism, resulting in undesirable products, some of which could be toxic to other life forms. Some biopesticidal traits conferred through GE could be fatal to susceptible nontarget species. For instance, traits that result in sterility, if applied to insect pests or fishes and passed on though outcrossing, could eliminate certain species, leading to ecological imbalance. Situations could also arise in which mistakes were made, particularly with microbes used in research, whose disposal could lead to massive contamination of water and soil, which would be difficult to rectify and would have detrimental consequences for public health.

Smallholder producers and traders dominate southern African agriculture. In smallholder communities, indigenous genetic resources are often valued for their adaptation to extant conditions and for their medicinal utility. Governments in the region, keen to preserve these traits as public goods, view biotechnology as posing potential barriers to such aims.

Also significant in the region are the risks that biotechnologies may pose to trade, and thus to a range of social welfare concerns. Many governments believe that food imports must not pose risks to human health and the environment. And exports must meet importer's health and environmental requirements.

The International Status of Biosafety

The Cartagena Protocol is a supplement to the Convention on Biological Diversity that seeks to address issues surrounding the safe transfer, handling, and use of living modified organisms (LMOs) resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity in the context of risks to human health, specifically focusing on transboundary movement (CBD Secretariat 2000). Under provisions of the protocol, member countries have an opportunity to assess risks associated with products of GE and indicate their willingness to accept agricultural commodities that include LMOs. Effective implementation of the protocol is linked to the development of national biosafety systems; hence the present efforts to assist countries and regions to develop biosafety regimes. The UNEP-GEF global project on the development of national biosafety frameworks is one such effort (McLean et al. 2002).

The concept of biosafety relates to the World Trade Organization's agreements on sanitary and phytosanitary measures and technical barriers to trade, both of which are about detecting and managing risks for an agricultural trade environment and require risk assessments for decisionmaking support under free trade arrangements. Biosafety provisions also relate to the Codex Alimentarius of the Food and Agriculture Organization and the World Health Organization, which provides voluntary standards on traded food substances.

The general principles of risk or safety assessments were first established by the Organization for Economic Cooperation and Development (OECD 2000). The technical features of practices to assess and manage risks comprise knowledge of the nature of the organism, its products, and distinguishing features of the process by which the product is produced and the environment into which it will be introduced. These are scientifically evaluated on a case-by-case basis once stakeholder concerns have been identified, thereby enabling regulators to identify risks and make recommendations. This implies a requirement of developing new capacities in policy, taking stakeholders on board, and establishing regulatory structures and services. Returns on the development of such systems are maximized if the systems are aligned with international agreements governing movements of genetically modified organisms (GMOs).

The Status of Biosafety in the SADC Region

The biosafety regimes presently in place in the various SADC member countries have to do with conventional pest and disease control in plants, man, and animals; they consist of policies and practices dealing with environmental conservation, food, prophylactics, drugs, cosmetics, and toxic substances. These frameworks require updating or complementing to address products of modern biotechnology.

New products from modern biotechnology still need to be evaluated for their differences from or similarities to known equivalents in terms of their value, safety, and risk. While research has developed modifications for crops grown elsewhere, evaluation of local varieties developed over decades of breeding research is still necessary. Local evaluation also will yield data relevant to local ecosystems. Presently only Malawi, South Africa, and Zimbabwe have biosafety regulations suitable for managing limited or open releases of GMOs. A summary of the status of development and implementation of biosafety systems in the SADC region as of 2001 is given by Mnyulwa (2001). Findings of a southern and eastern African regional workshop on biotechnology (Mswaka, Masimbe, and Mnyulwa 2001) indicated that lack of relevant policies was among the major limitations to the introduction and use of molecular biotechnology. However, an analysis by Cohen and Paarlberg (2002) concludes that nontechnical issues seem to be the deciding factor in the low level of adoption and commercialization of GM technology in developing countries. For Botswana, Namibia, and Zimbabwe, which benefit from a preferential niche market for their beef exports in the European Union, fears of a loss of this prime market contribute to the low level of adoption or reluctance to adopt the technology. A SADC fact-finding mission early in 2003 confirmed that this fear emanates from a European consumer position that is strongly against GM foods for human consumption. While Zimbabwe has biosafety regulations in place, capacity issues may prevent the mainstreaming of testing for genetic modification in meat from beef fed GM feeds, in support of exports.

An approach to setting up biosafety systems is therefore required. Its aim would be to clarify nodes in a decision tree, assess policy alternatives, separate scientific issues from nonscientific ones (McLean et al. 2002), and provide a basis for action plans. A biosafety system will support the already strong seed industry as well as plant and animal genetic resource conservation programs that are in place. Key questions to be addressed include these: Should individual countries develop a national capacity for scientific risk assessment, or should such capacity be developed and coordinated regionally? Should biosafety regulation be centralized in one agency, or should it be distributed among a number of bodies? Should policy harmonization take the form of congruent legislation, or should it merely comprise shared "checklists" of essential elements? When should information about the outcomes of risk assessments be published, and in what forms?

A Biosafety Framework for the SADC

The SADC's 14 member states share objectives for national development based on regional cooperation and integration. The community's Food Agriculture and Nat-

ural Resources Sector program aims to meet regional agricultural and natural resources policy objectives revolving around enhanced food security, improved trade, sustainable use of natural resources, and coordinated responses to natural disasters such as drought, floods, and agricultural pests. Mozambique, South Africa, Zambia, and Zimbabwe now enjoy joint actions in managing transfrontier nature parks, emphasizing regional cooperation in the use and conservation of the environment. Through regional cooperation, arrangements for strengthening regional management of transboundary animal diseases and pests supported by quality-accredited testing facilities are under development. Implementation of the Cartagena Protocol will therefore reinforce management of transboundary issues in biosafety from a technical and social standpoint.

McLean et al. (2002) outline a five-point framework to address national needs for countries that are party to the Cartagena Protocol. Table 5.1 represents a preliminary attempt to develop a biosafety framework for the SADC region, building in part on the framework of McLean et al. (2002). This proposed framework is based on a logical process in which an assumed prior position (default or policy position, column 1) is queried through key questions (column 2) about how it will be attained. Depending on how the key questions are answered in the responses (column 3) if answers are necessary, a list of what is to be done (policy instruments, column 4) is stated. Some of the identified policy instruments may need to be further queried, forming a second tier of the decision tree. In the example offered in the table, such policy instruments are marked with an asterisk and brought to column 1 to start the process in the table. The trade-offs in column 5 provide an opportunity to compare exclusive options to enable decisions to be made. A group of stakeholders may treat this exercise more exhaustively in order to maximize the number of questions and trade-off positions suggested. The table shows an example that is likely not exhaustive.

This example complements the global United Nations Environment Program–Global Environment Facility (UNEP-GEF) project on the development of a national biosafety framework (Briggs 2001). It targets the policy environment, including biosafety research agendas and strategies; the resource and knowledge base necessary to assess status and gaps, including capacities and skills; and the development of regulations and implementation of procedures outlined in authority instruments, processes, and procedures for a biosafety system. Having biosafety regimes in place creates a managed environment for the introduction of modern biotechnology, access to products from it, and research and testing that use biotechnology tools. Such a regulated, managed environment creates the confidence required by entrepreneurs and industry, consumers, traders, and those who have responsibility for the technology. It also fosters the development of modern

Table 5.1 Draft of proposed policy development framework for biosafety in the Southern African Development Community

Policy position taken	Key questions	Response	Policy instruments	Trade-offs
No position taken on biosafety	Are measures taken to safeguard the environment and human health?	No	Nil	Indiscriminate and unethical use of biotechnology with threats to human and animal health and the environment Social and political dissent with no recourse Difficulty of meeting demands made by countries with biosafety policies Difficulties with trade partners that affect trade
		Yes	Ad hoc and situational	Actions not well thought out, with negative consequences for food security, technology transfer, resource mobilization, loss of trade opportunities, etc. Poor planning and prioritization of actions Difficulty in monitoring the status and activities of biotechnology Difficulty in coordinating bilateral protocols on biosafety Lack of political commitment that undermines the success of situational decisions
Adopt biosafety policy for bio-technology and biosafety under containment	Is there a need for biotechnology under containment? Are authorization channels in place? Are technical capacities available?	Yes	Implement authority, mobilize capacities, and oversee testing and trials Regionalize trial sites	Low public support with absence of direct perceivable benefits to the people (theft of produce, etc.) High investment cost in equipment and personnel, with no prospect of returns by interested parties
		Need identified but no authority or capacity	*Design enabling legislation and regulatory instruments and implement them Prepare and train personnel to create capacities for inspections and reporting *Establish decisionmaking and advisory bodies	Long waiting time for legal drafting or repeals and revision Numbers of relevant expert scientists low
	Do we know what is being safeguarded?	Yes	Support SADC plant genetic resources center with molecular characterization and bioinformatics Support conservation at the local level	High investment cost No system yet for animal genetic resources

	Do we know whose interests are being safeguarded?	No	Conduct surveys and field collections and create distribution maps of germ plasm for reference and in situ conservation Establish bioinformatics nodes for local germ plasm (both plant and animal) Establish database of GMOs under test, along with information and decisions pertaining to them Enlist support of the public or farmers who know, use, and are custodians of natural germ plasm Generate information on food safety and human health risks and benefits and provide to public	A slow process due to capacity needs High chances of slow uptake by the public due to highly technical content of subject Perceivable benefits to communities rather small and difficult to grasp
	Are there provisions to deal with cases of noncompliance? Are the provisions enforceable? Can results from one country be used in another?	No	Design regulations for trials under containment and for reporting of data generated Stipulate liability, redress, and reparation in regulations Take measures to ensure adequate capacity Use harmonized procedures in all countries	Capacity problems with legal personnel Reparation unachievable with some types of gene escape Regulations a disincentive for researchers and investors
Adopt policy for commercialization	Are there any potential benefits and risks from the products or process? Can these risks and benefits be scientifically proven? Are long-term risks assessable?	Yes	*Establish objective measures for benefits and risks for use in informing decisions *Separate scientific and nonscientific risks and benefits for decisionmaking and advice Conduct population epidemiological follow-ups Conduct impact assessment for farming systems and the environment	Some risks and benefits may remain unperceivable Some risks are not measurable using routine laboratory analyses (e.g., some unintended toxins produced in a process despite achieving intended product) Capacity and expertise not sustainable
	Who is affected by this policy?		Inventory stakeholders	Some groups are too diverse and difficult to represent (e.g., farmers: small, medium, large, organic, etc.)
	Are there tracking methods for commercialized (approved) versus unapproved equivalents? Is information about the range of developed GMOs available?		Use reliable standardized test methods Sustain human resource expertise Maintain database of approved GMOs Establish a monitoring system based on transparent information provision by source by means of advance informed agreement principle	Reliance on test protocols developed elsewhere Mutations could occur in local adaptation Cumbersome monitoring system

(*continued*)

Table 5.1 (continued)

Policy position taken	Key questions	Response	Policy instruments	Trade-offs
			Stipulate what is to be monitored (imports, exports, goods in transit, etc.) Identify reliable information source, capturing technology changes and further GM modifications on approved ones	
*Develop biosafety legislation	Are some existing laws closely associated with biosafety?	Yes	Review them and modify if necessary	Difficulty of modifying several different laws relating to biosafety, some under control by different sectors
		No	Draft new law specific to biosafety	Long time (in years) required, and investment opportunities may be lost to other countries or regions
	Are associated laws in the same sectors?		Define lead sector where related laws are in different sectors	Conflict with other sectors Differences in capacities in different sectors and biases resulting in advice and decisions
	Do we know which sector will implement biosafety laws?		Define competent authority for biosafety issues	
	If in different sectors, do we know how food and agricultural issues will be attended to?		Appoint biosafety focal points for each sector and a lead focal point to coordinate	Difficulty in accessing information from other sectors Difficulty in coordinating cross-sectoral matters Challenge to authority over other sectors Conflict among personnel from different sectors Turn-over of human resource Difficulty in attaining unison at regional level
	Can laws be effectively implemented?	Yes	Design regulatory instruments and quality-assured auditable action plans and procedures	Need to call on external expertise for service audits Countries may take years to develop laws to be harmonized
	Can laws be effected at the regional level? At the international level?		Harmonize laws at the regional level and with the Cartagena Protocol, the Food and Agriculture Organization–World Health Organization codex, and the World Trade Organization and implement through protocols	Need to develop capacity to develop and harmonize laws
	Are the affected members of the public involved?	No	Stipulate use of participatory policy development (social engineering) to maximize ownership	Participatory approaches take time, and there is no guarantee that the outcome will be uniform
	Do we know at what stage the members of the public are to be involved?		If not involved, predetermine points at which members of the public are informed	Informing the public is command controlled, and policy ownership is not ensured

	Do certain groups need to be targeted (e.g., farmers, urban consumers, frontier communities, travelers, etc.)?			
Research and testing	Are policy decisions and regulations guided by scientific evidence?	Yes	Support for priority biosafety research and development (R&D) Use of evidence in *decisionmaking	Heavy cost of R&D may result in reliance on external evidence sources
	Will locally relevant issues be researched for the benefit of the region?	Yes	Support R&D for orphan commodities and local knowledge-based biotechnology for competitive advantage Conduct policy research on the impact of biosafety	Capacity and cost issues Local entrepreneurs may not be quick to realize opportunities Likely to be a long-term action
	Is there capability to conduct tests and trials in regional interests?	No	Do human resource development in biosafety (*risk assessment, research, legislation) Rely on external sources	Regional inequalities cause discomfort in training in only a few countries in the region Relevance problems if focus is not on issues of direct regional interest
	Are resources available for biosafety research?	No	Biosafety research investment position for countries and the region	Competing needs and lack of sustainability for ongoing priorities in research
*Advice and decisionmaking	Do we know how decisions can be made and communicated for implementation? Do we know who has the final say on decisions made? Do we know where information about decisions will be kept?	No	Clarify roles of biosafety focal points, advisory bodies, decisionmakers, regulatory authorities, and reporting structures Clarify roles of expert or advisory committees and the biosafety information hub in communication	Cross-sectoral interests and information leakage Loss of confidentiality by involving the public
*Risk assessment	Are there local capacities to do risk assessments? Do we know what actions will be necessary for products registered elsewhere?	Yes	Appoint institutions or individuals to undertake risk assessments Employ validated auditable procedures based on international norms	Empowered regulatory institutions may not have the required expertise Products may not be in use where registered Products of interest may not be tested elsewhere

Source: Adapted from McLean et al. 2002 by author.

Note: Asterisks (*) denote policy instruments that need to be further queried, forming a second tier of the decision tree. Policy instruments so marked are brought to column 1 to start the process in the table.

biotechnology within a country, ensuring access to biotechnology products from elsewhere (Persley, Giddings, and Juma 1993). Within the regional context, biosafety regimes are important whether or not products of biotechnology are accepted. Recently a number of countries in the region accepted GM food aid, in most cases before biosafety policies and frameworks were in place. This led to ad hoc decisions ostensibly in the interest of the public and environmental safety. In countries where biosafety regulations were in place, they were invoked for the first time for import commodities, and GM maize could be subjected to strict movement inspections and mandatory milling at ports of entry before distribution.

Land-locked countries may need to use transit routes through neighboring countries to get products to their territories. In addition, certain environmental risks such as those posed by microbes and pollen drift will transcend territorial boundaries, making it necessary to monitor local environments for the presence of unwanted genes. This function will depend on well-managed information systems for coordinated actions.

Biotechnologies are already available in a number of countries of the world, and the SADC region can regulate either to keep them out, in which case it still needs technical capacity and analytical understanding, or to accept them. Multinationals involved in commercial applications with GMOs are applying to test their technologies toward introduction for trials or product development, particularly of seed.

The needs of researchers must also be addressed. Individual countries may wish to accept the technology as a tool only for research and testing or one for research, testing, and commercialization. Either way, biotechnology is unavoidable, and the minimum a country will need will be testing ability that must be accompanied by a biosafety regime for handling a given genetic event, with which reliable diagnosis of GM will be made.

Challenges to Biosafety Policy

Public policies are statements of intent about what is to be done by states or agencies. They are outcomes of interactions between the states or agencies and civil society. Policies are therefore intended to serve the public interest. They are expressed as acts of parliaments or congresses or as regulations that attempt to state in very clear and specific terms what is to be done under various circumstances surrounding an issue. Policies may further be explained for relevance through statutory instruments, guidelines, strategy documents, and action plans. Policymaking in the SADC, as in most developing countries, has tended to be a prescriptive and top-down process rather than one accomplished with public participation. This is due to the

low level of literacy that usually obtains, to ignorance about the purpose of policies and regulations, and to the absence of skills in participatory development techniques and the anxiety of administrations eager to bring about changes without committing too much time and financial resources, who therefore implement policies and regulations by force rather than by voluntary cooperation. Although a top-down approach may have worked in developing most past policies, there remains a level of ignorance about the meaning of these policies, as their derivation may not be well understood by the public they are intended to serve. Mandaza (2003) attributes a further difficulty of policymaking in most SADC countries to low levels of interaction across social classes separated by income differentials, which are themselves confounded by race and ethnicity.

Further challenges appear upon recognition that within countries several government ministries are likely to be involved in the policymaking process, each with a different politically motivated position. Ministries of the environment tend to be against biotechnology, normally under pressure from environmental stakeholders and the general conservatism of the United Nations Environment Program, where the environmental agenda is set. Ministries of agriculture (and the national agricultural research institutes that they usually house) and national scientific councils are typically more progressive and would like scientific positions to hold sway. Ministries of trade are conservative and are especially concerned about future prospects for trade with Europe. Ministries of health are conservative and are concerned about implications for human health. Major political logjams can occur. Even when these hurdles have been overcome and legislation has been enacted and is in place, there is typically insufficient capacity in most countries to handle the avalanche of testing that ensues. These capacity constraints are addressed later.

Disparities also exist across countries at different levels of overall economic development—differences that are often determined by and reflective of differences in science and technology policy frameworks. This leads to insecurity in some countries, based on fears of losing revenues and job opportunities and on fears of marginalization and domination of the weak by the strong, which militates against harmonization and collective approaches (*SADC Review* 2001).

Public Involvement

Millions of southern Africans live in poverty in both rural and urban areas. This is in marked contrast to conditions in developed countries where the middle classes dominate, where views about acceptable and expected lifestyles and standards of living are widely held, and, most important, where levels of awareness of public issues are high. The level of public involvement in policymaking is therefore often

high, including that relating to biotechnology and biosafety. In contrast, large sections of the public in southern African countries remain totally unaware of biotechnology and biosafety. Those who are aware often hold narrowly defined positions that may be based less on evidence than on politics. For instance, deeply held positions against biotechnologies are often driven by suspicions that countries of the North are using those in the South as dumping grounds for experimental products to provide them with more information before these products can be fully commercialized for use in the North. Instances of public policies supporting exports of toxic waste matter from the North to the South add credence to such positions, which are further strengthened by the increased speed with which information spreads around the globe.

More than 60 percent of the SADC population is engaged in farming, which is closely tied to environmental issues. Food is both formally and informally transported between and within countries. Mechanisms are required to empower citizens by giving them correct understandings of the concepts of the science so that they can articulate and communicate their desires to further the aim of achieving effectiveness and transparency (Cohen 2001). The involvement of the public helps in identifying concerns as well as in seeking ways to address the concerns. It also allows accurate, factual information to be disseminated, thereby dispelling myths spread by rumors (Persley and Doyle 1999).

Public involvement also allows communities to own the process of monitoring their environments for unscrupulous activities and assists regulatory processes through self-policing. Nontechnical issues are crucial to the success of biosafety. Understanding these issues will make it easier for the public to internalize the intentions of regulatory requirements, putting them in a position to assist the often resource-strapped government departments by exercising self-policing on issues related to safeguarding the environment and their health and safety from unwanted or unapproved products.

Of particular concern in this regard are communities who live near frontiers. The frontiers in the SADC are barely 150 years old, established only since the partitioning of Africa. Most are artificial, and the people they divide often belong to the same clans and cultures, so they share heritages, have mutual family connections, and may intermarry. As a result, they often disregard borders, to the detriment of the effectiveness of policies in the countries on either side of these borders.

Another concern related to the safety of the environment is that measures are needed to prevent accidental exposure as goods are transported through foreign territory to reach inland destinations, some of which are land-locked.

The languages of official communication in most of the SADC are foreign, mostly English and to a lesser extent French and Portuguese. Scientific education

and laws are written and communicated in these languages. However, more than 70 percent of the region's populations are rural, and in a majority of the countries more than 30 percent are illiterate (SADC Review 2001). Even among the urban dwellers, there are indications that a majority are more comfortable learning concepts and better understand them when using local languages. Local language equivalents still need to be identified for scientific terms.

Capacity

The science itself is relatively new, and only South Africa and Zimbabwe have formal tertiary-level courses. Most biotechnologists have therefore been trained in Europe or North America and are still too few. An even smaller proportion of scientists with training in related disciplines aspire to policymaking positions. The capacity to address public programs in science and technology areas has been affected by high staff turnover due to governments' inability to give staff commensurate rewards and conducive conditions of service. Over the last two decades attrition rates among the highly competent and able-bodied, who comprise the majority in the technical and regulatory professionals, have been rising due to HIV/AIDS as well as the attractions to work under the better-endowed conditions enjoyed at their places of training. High staff turnover affects the ability to sustain policy strategies and actions, critically analyze issues and provide useful advice, and articulate needs, as well as the ability to review and modify the requirements.

Legal services and associated analytical processes are thwarted by a shortage of legal professionals with an understanding of biotechnology. Biotechnology and biosafety know-how may not yet be resident among regulatory service staff. The SADC already lacks institutional capacity at both the national and the regional levels, resulting in a failure to adopt appropriate time-bound performance indicators for its protocol ratification processes and programs (SADC Review 2001). A number of initiatives by regional nongovernmental organizations, including the Southern African Regional Biosafety Initiative and the Regional Agricultural and Environmental Initiative (RAEIN-Africa) aim to address identified scientific capacity and public empowerment, respectively, in biosafety. The UNEP-GEF facility is also assisting with policy formulation and capacity building in some member countries such as Malawi and Namibia.

Financial Resources

Given the poverty levels and increasing fiscal shortfalls of the SADC, traditional funding from member country contributions might fail to meet the requirements.

This factor is likely to compromise concerted actions for biosafety. Policies are more effectively implemented if accompanied by resource allocations. New policies therefore call for additional resources. Investments in public biotechnology and biosafety research could be increased directly by the member states and indirectly through regional collaboration and international partnerships (Cohen 2001) including the private sector as stakeholders. Most donor agencies and investors seem to be increasingly in favor of regional approaches to development.

Interest expressed by multinational companies in registration of their GMO products could be turned into opportunities for resource mobilization for research trials and data accumulation. Issues bordering on conflict of interest will need to be addressed. Local private industries that might benefit from the technology will need to exploit partnerships with the public sector and its agencies to expedite progress in their interest.

Recommendations

The following are my general recommendations related to biosafety policy in the SADC region:

1. The suggested policy framework (Table 5.1) should be considered in order to define appropriate policy alternatives suitable for regional biosafety management toward a ratified protocol.

2. Strategic action plans should be developed to realize the objectives set out to address selected policies.

3. Structures for decisionmaking should be based on benefits and risk assessment, with scientific and other stakeholder concerns used in directing policy instrument design and implementation.

4. Systems to effect regulatory oversight, including quality-controlled and -assured testing for genetic modification, should be developed and introduced.

5. Stakeholder participation in defining biosafety instruments and their objectives should be enhanced.

6. Member countries should be urged to design policies and actions that can be extended into regional and international arrangements.

7. Member countries and the SADC should review their resource base to ensure that they can make effective commitments to allow biosafety processes to begin taking effect sustainably.

8. Member countries and the SADC should review existing biosafety mechanisms, infrastructure, and the human resource base in order to determine which functions can begin immediately and which can be phased in over time according to a schedule.

9. Regional efforts to enhance biosafety research and testing should be promoted to reliably inform regulatory authorities and other regional decision-making structures in order to facilitate movements and trade involving GMOs.

10. Investments should be made in the necessary regulatory, advisory, technical, and legal services in order to identify gaps in biosafety skills and take steps to close those gaps.

11. Investments should be made in systems for the retrieval and exchange of relevant information in order to establish national and regional biosafety information nodes for storage.

12. The legislation and regulatory mechanisms adopted should be sufficiently flexible to account for the dynamism of biotechnology and biosafety and for their rapid development.

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