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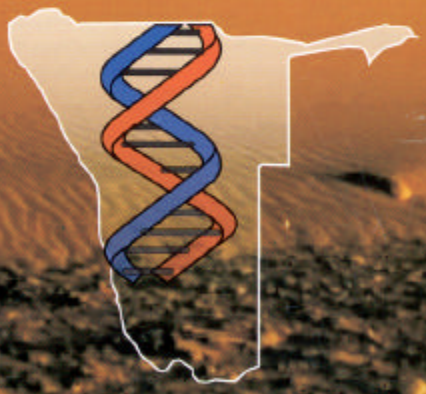
NATIONAL POLICY DOCUMENT

ENABLING THE SAFE USE *of* BIOTECHNOLOGY



Based on the Work of the Namibian Biotechnology Alliance

Republic of Namibia

National Policy Document

ENABLING THE SAFE USE OF BIOTECHNOLOGY

Submitted by the

Ministry of Higher Education, Vocational Training, Science and Technology

Based on the Work of the Namibian Biotechnology Alliance (NABA)

October 1999

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National Policy Document
Enabling the Safe use of Biotechnology

Biotechnology in perspective

The rapidly expanding world population has placed pressure on renewable and non-renewable resources, leading to an over-concentrated use and degradation of some resources. This situation was identified as a major focus of the *United Nations Conference on Environment and Development* held in Rio de Janeiro in June 1992.

At that historic conference, the *Convention on Biological Diversity* (CBD) was opened for signature. The Convention is an important international tool for the effective management and sustainable use of the world's biological resources by present and future generations.

Namibia's Constitution, its National Development Plan and policies are especially far-sighted and progressive with regard to sustainable development and environmental protection. It is essential that the political will and foresight to continue on this road remain, in the face of current international economic and political pressures to employ high technology prematurely in the provision of health, food and shelter.

Namibia, represented by His Excellency the President, was one of the original signatories to the Convention on Biological Diversity, and Parliament ratified this decision unanimously on 18 March 1997. Currently the Parties to this Convention are in the process to develop the protocol on Biosafety, in order to provide international agreed standards for Genetically Modified Organisms (GMOs). This policy underlines the Government's commitment to the conservation of biological diversity and sustainable use of natural resources, which incurs a responsibility to regulate the use of modern biotechnology. Biotechnology may have both positive and negative impacts on society, the economy and environment, and is therefore specifically addressed under the Convention.

The products of biotechnology are increasingly relied upon to meet demands for food, shelter and health by an expanding global population. The development and commercialization of biotechnology has become a major industry worldwide. The long-term impact of some of these technologies is often not fully understood prior to large-scale use.

It is thus of the utmost importance that decisions on the use of these technologies are based on scientific, economic, social and ethical evaluation.

The selective planned use of modern biotechnology in Namibia can potentially lessen the impact of our growing population on finite and over-exploited natural resources. However, they can be considered tools for sustaining the population and its development.

Namibia's National Biosafety Framework must strike a balance between the regulation and promotion of biotechnology. Risk-benefit and cost-benefit evaluation of individual applications should be undertaken, in full consideration of Namibia's particular biophysical and socioeconomic environment.

Like most developing countries, Namibia does not have the financial resources to duplicate existing sub-regional, regional and global institutions and structures. Networks of co-operation, collaboration and information exist on these levels in the biotechnology arena, and Namibia can make effective use of these. However, decision- making must be nationally driven throughout the process.

It is an immediate priority to develop national institutional and human resource capacity so that Namibians can decide on biotechnology applications. Developing nations hold the major concentrations of the world's biological diversity, and its richest centres of genetic diversity. While the judicious use of modern biotechnology for Namibia's socio-economic development may prove desirable for food, fibre and fuel production and waste disposal, certain biotechnology applications, practices and products may seriously jeopardise the health of Namibia's human population or natural environment, including its immensely valuable biodiversity resources. Therefore, the Republic of Namibia:

recognising the utmost importance to make use of the potential country's environment by protecting its biological diversity in order to promote national sustainable social and economic development through appropriate technologies.

recognising the human and environmental health risks that may be incurred by careless or unscrupulous practices in the development, use or trade of biotechnology products for agricultural, health, waste management and other purposes;

recognising the utmost importance of developing own capacities related to biotechnology and biosafety through the research and development (R&D) communities;

reaffirming its commitment to the principles of the 1992 Rio de Janeiro Declaration on Environment and Development, especially

A liability and compensation for environmental damage, including that caused by transboundary incidents or processes (Principle 13) and

B the 'precautionary principle,' in which a lack of reasonable scientific certainty about environmental or human health risks shall not be used to justify avoiding or postponing cost-effective measures to prevent these risks (Principle 15);

reaffirming its commitment to the principles of the *World Trade Organisation* (*WTO*) agreements, specifically in relation to *Technical Barriers to Trade* (*TBT*);

reaffirming its commitment to the principles and aims of the *Convention on Biological Diversity* (*CBD*), especially

A	Article 3	(Principle of sovereign rights and responsibilities);
B	Article 8g	(Control of risks associated with genetically modified organisms);
C	Article 14	(Assessment and minimisation of environmental impacts);
D	Article 15	(Access to genetic resources);
E	Article 16	(Access to and transfer of technology);
F	Article 19	(Handling of biotechnology and distribution of benefits);

states the following national policy principles for the safe use of biotechnology.

1. PRINCIPLES

A. Namibia has sovereign rights over natural (including genetic) resources in its area of jurisdiction, and authority to control activities, which exploit or may have deleterious impacts on such resources. As Party to the CBD and the *United Nations Conference on Environment and Development*, Namibia is explicitly obliged to control biotechnology applications, which may harm its biological diversity and human health.

B. Namibia shall endeavour to strike an appropriate balance between biotechnology promotion and regulation in the sustainable development pathway of Namibia.

C. The use, import, export, sale or transit of biotechnology applications, practices and products must conform fully to all existing national legislation.

D. The formal regulation of biotechnology shall be by a competent authority advised by a technical body independent of both government and industry, whose decision-making process is transparent, takes full account of environmental, public health, socio-economic and socio-cultural concerns, is based on locally applicable scientific and other data, and applies the precautionary approach.

E. All costs involved in the decision-making process, including running costs and field trials shall be financed by the applicant, unless otherwise agreed by the Government of the Republic of Namibia.

F. Biotechnology applications based on or inspired by the knowledge, innovations or practices of communities or individuals in Namibia shall be subject to national legislation related to community or individual intellectual property rights, and shall incorporate contractual agreements to share financial or other benefits arising from such applications with these communities or individuals. The State shall facilitate community access to appropriate advice for the purposes of negotiating and concluding such contractual agreements.

G. Namibia shall endeavour to co-operate with other States, particularly its neighbours, to ensure the safe use of biotechnology within its borders.

H. Namibia shall not permit the importation or use of biotechnology products and procedures, which do not meet minimum safety standards identified by the competent authority as stated in this policy document. Namibia shall endeavour to implement local field trials of such products or procedures to the extent of its ability, financed by the applicant, where existing data are regarded as inapplicable to local circumstances.

I. Where scientific risk evaluation of a biotechnology product, application or procedure gives rise to a negative recommendation, this shall not be overruled for reasons of political or economic expediency; but a positive recommendation may be overruled on political or economic grounds.

Pending the outcome of global and regional assessments of the severe potential socio-economic, ethical, and environmental risks posed by "Genetic Use Restriction Technologies" (GURTs), Namibia shall enforce a five-year, renewable moratorium on the import, export, sale, or use of genetic material, such as seeds, altered by these technologies, including the so-called "Terminator Technology" and related processes. Such moratorium shall take immediate effect on the acceptance of this policy by Cabinet. A publicly transparent annual review of this moratorium shall be conducted by the Namibian Biosafety Advisory Council (section 3.2.1.1).

2. OBJECTIVES

2.1 National development objectives

The Government of the Republic of Namibia is dedicated to achieving genuine reconciliation through the pursuit of its long -term goal of political equality, social justice, human dignity and equal opportunities for all citizens as manifested in the Constitution of the Republic of Namibia.

In order to attain its long-term goals, the government has formulated four broad national objectives:

- to revive and sustain economic growth;
- to create employment opportunities;
- to alleviate poverty; and
- to reduce inequalities in incomes

This policy offers guidance for sustainable development by providing for mechanisms to ensure the safe use of biotechnology so as to strengthen the economy and enhance human livelihoods without prejudice to public health, environmental health, national sovereignty, human dignity or fundamental human rights.

2.2 Biotechnology and biosafety objectives

The two main goals of Namibia's national policy on biotechnology and its safe use (hereafter *biosafety*) are:

- to guide the judicious use of modern biotechnology in Namibia for sustainable development, in ways which do not in any way jeopardise human or environmental health, including Namibia's biodiversity and genetic resources;
- to ensure effective control of transboundary movements of genetically modified organisms or products thereof resulting from modern biotechnology, through the exchange of information and a scientifically based, transparent system of advance informed agreement.

In particular, the national policy shall:

A Provide for the establishment of a permanent participatory planning process to feed into regulatory decision-making on biotechnology for the promotion of sustainable development.

B Support the development of regulatory capacity to assess, test, monitor and control biotechnology applications in accordance with agreed biosafety guidelines.

C Support the development of research and industrial capacity to safely apply biotechnology techniques for the enhancement of Namibia's socio-economic and environmental well being.

D Provide an institutional framework for national decision-making and international co-operation in this area.

3. POLICY FRAMEWORK

3.1 Scope

This policy covers all GMOs and their products. This coverage includes all living organisms, germplasm, and all elements of genetic material used in genetic manipulation.

This national policy covers in detail:

a) laboratory and field applications of biotechnology within Namibia, whether currently known to science or those developed in the future;

b) the fields of agriculture, human and veterinary medicine, food / beverage production, industry, environmental management, bioremediation of mining, industrial and domestic wastes, and other fields of current or future application;

c) the regulatory process, including notification, information transfer and review, risk assessment including socio-economic impact and ethical considerations, monitoring and enforcement measures pertaining to import or export of the products of biotechnology, or laboratory or field use of biotechnology in Namibia, including handling, disposal, containment, control, monitoring and release;

d) the biotechnology research and development process, including academic, agricultural, industrial and other research;

e) occupational safety at workplaces where biotechnology procedures are used or products handled;

f) labelling of genetically modified organisms in foodstuffs and feeds sold in or imported to or through Namibia;

g) any other measures to ensure public health or environmental safety with respect to the use of biotechnology in Namibia or its neighbouring territories or waters.

3.2 Implementation strategy

This policy attempts to strike a balance between protection and promotion. This can happen only with a clear, balanced and supportive policy, legislation, and a better-informed public. It is not in Namibia's interests to be used to test, purchase, or dispose of products or technologies, which are, banned elsewhere, or which fail the safety standards of other nations. Adjusted measures are needed to ensure Namibia's sustainable development with regard to:

- environmental resources;
- economic resources;
- appropriate technologies;
- corporate investment and rural peoples' rights and livelihoods;
- improved food security through biotechnology and through the use of agricultural genetic resources.

Those measures must incorporate mechanisms for flexibility, so as to adapt to our current and future needs.

The policy outlines a national institutional framework for regulatory, administrative, research and development activities in the field of biotechnology.

3.2.1 Institutional framework

Two participatory national workshops held in early 1999 strongly endorsed a biotechnology capacity for Namibia. This strategy necessitates a sound institutional framework, with urgent attention to increased regulatory and enforcement capacity.

3.2.1.1 Regulatory and administrative structures

Regulatory and administrative processes include notification, information transfer and review, risk assessment, approval or refusal, risk management, including monitoring and enforcement measures pertaining to laboratory use, research and development activities, or field release procedures including handling, containment, monitoring, agreed disposal or destruction procedures, and contingency plans for spillage or accidental release. In order to trace GMOs at the point of import, sectoral legislation related to import control may require appropriate amendment and enforcement.

Internationally, biotechnology applications are used in the fields of agriculture, human and veterinary medicine, food / beverage production, mining and bioremediation, waste management and others. Risk assessment therefore is primarily the responsibility of agencies tasked

with environmental protection, public health, occupational health, and food safety. Therefore, although the Ministry of Higher Education, Vocational Training, Science and Technology (MHEVTST) shall be the competent authority, regulatory input is also the responsibility of the Ministry of Environment and Tourism (MET), Ministry of Agriculture, Water and Rural Development (MAWRD); Ministry of Health and Social Services (MHSS); Ministry of Mines and Energy (MME); Ministry of Trade and Industry (MTI); and Ministry of Labour (ML). Major advisory responsibilities are expected to lie with the MET, MAWRD and MHSS. Because border control is a crucial element to restrict the movement of genetically modified organisms across Namibia's borders, the Ministry of Home Affairs (MHA) will have enforcement responsibilities. A priority need is to train border control, police and customs officers to search for and recognise potentially genetically modified material, with mechanisms established to screen suspect material. Labelling regulations on imported material will be central to the success of these inspection and enforcement functions.

Regulatory competence exists in the following areas, although all areas need specific strengthening:

- MAWRD: agricultural law enforcement (including sanitary and phytosanitary import/export control), crop and livestock disease control, registration of livestock importation and agricultural products;
- MET: environmental impact assessment and permit review functions;
- MHSS: public health impact assessment and food safety review functions;
- MTI: industrial practices review and import/export management functions;
- ML: occupational safety standards review functions;
- MF: customs and excise functions;
- MHA: border control and forensic science;
- MHEVTST: policy integration and institutional coordination functions;
- MFMR: marine resource management, stock assessment and input to impact assessment processes.

In all cases, there is an urgent need for awareness-building and detailed training exercises, following institutional capacity needs assessment.

3.2.1.2 Interim structures

The Ministry of Higher Education, Vocational Training, Science and Technology (MHEVTST) shall act as the competent authority, with the elected Management Committee of the Namibian Biotechnology Alliance (NABA) as the *interim* technical review and advisory body. The MHEVTST shall liase closely with all relevant institutions listed below, with recognition of Namibia's National Environmental Assessment Policy of the Ministry of Environment and Tourism (MET) and any other relevant legislation. Applications to import or use biotechnology products or procedures shall be processed by NABA, which shall consult international and/or local experts as required to reach sound decisions on the desirability and risks of all applications. This process shall be conducted on a fast track or full review basis (section 3.2.1.2).

3.2.1.3 Permanent structures

Upon acceptance of this policy and supporting legislation, a permanent advisory body shall be established, known as the Namibian Biosafety Advisory Council (NBAC).

The NBAC shall be an independent, transparent technical advisory body, with the MHEVTST as government competent authority. Its Chairperson shall advise the Minister of MHEVTST directly. The NBAC shall receive and process applications on a fast-track or full review basis (section 3.2.1.3) and convey the decisions and supporting materials to the Minister of MHEVTST, who shall be formally responsible for all such decisions. The MHEVTST shall establish a small National Biosafety Inspectorate (NBI) unit to carry out inspection activities.

Members of the NBAC shall include adequate expertise in human and veterinary medicine, agriculture, plant breeding, microbiology or molecular biology, environmental protection, food production and processing, social sciences and economics, and any other field deemed necessary for fair and adequate evaluation of applications and reviewers' risk assessment reports.

3.2.1.4 Interim application and review procedures

Applicant submits proposal* to Registrar, NABA Management Committee

Registrar screens completeness and adequacy of proposal:

fast-track or *full-review*

Review by one specialist advisor

a: No likely impacts on neighbouring countries: review by 3 specialist advisors

b: Likely impacts on neighbouring countries: Review by 3 specialist advisors, and request any objections from neighbouring national advisory body

NABA Management Committee meets to consider referees' reports
Forwards recommendation to Director of interim competent authority (see 3.2.1.2)
Minister of interim competent authority issues formal decision to applicant

approval or *refusal*

initiation of proposal and self-monitoring

Appeal may be lodged (new supporting material) for re-review

Revised proposal may be submitted at any time (new design/ techniques only)

*Proposal must contain full details of import, research, containment, field release etc., including accidental release or spillage contingency plan and self-monitoring programme where appropriate. Competent authority may also request any other reasonable contingency information, including a cash bond deposited with Government. Competent authority may also specify regular reporting requirements and/or appoint an independent monitor for the project at the applicant's expense. If proposals require additional material or peer review the competent authority shall request these and pause its timetable for proposal processing until these materials are received. The processing time should be reasonable and justifiable.

3.2.1.5 Permanent application and review procedures

Namibia shall adopt the European Union's Contained Use System concept (Contained Use Regulations 2000), which holds that:

- genetically modified organisms (GMOs), especially genetically modified micro-organisms are classified according to their level of risk to human and environmental health;
- such classification be in line with sound international practice and based on risk assessment;
- containment and other protective measures must correspond with the classification of contained use;
- in cases of uncertainty, containment and other protective measures for a higher classification level should be applied until less stringent measures are justified by appropriate data;
- appropriate measures should be adopted and used for control of the disposal of material from contained uses of GMOs, in accordance with good microbiological and hygiene practice;
- these measures shall be reviewed periodically, to reflect the pace at which biotechnology is advancing;
- persons working with contained use systems shall be consulted about their occupational hazards;
- the desirability of a list of GMOs that are safe to human health and the environment should be considered;
- there now exists considerable information on the risks associated with the contained use of GMOs, particularly Genetically Modified Microorganisms.

The following four classes are thus recommended:

CLASS 1 Activities of no or negligible risk - for which level 1 containment is enough to protect human and environmental health.

CLASS 2 Activities of low risk - for which level 2 containment is enough to protect human and environmental health.

CLASS 3 Activities of moderate risk - for which level 3 containment is enough to protect human and environmental health.

CLASS 4 Activities of high risk - for which level 4 containment is enough to protect human and environmental health.

In all cases, uncertainty should lead to the use of the most stringent protective measures until sufficient evidence, by agreement of the NBAC, justifies the application of less stringent measures.

The following are considered "potentially harmful effects on human and/or environmental health": disease to humans, including allergenic or toxic effects; disease to plants, animals or other organisms; adverse effects resulting from the inability to treat disease or other effective prophylaxis; adverse effects resulting from establishment or dissemination in the environment; adverse effects resulting from the natural transfer of inserted genetic material to other organisms.

Applicant submits proposal to Registrar of the NBAC (three deadlines per year for receipt of proposals shall be set).

NBAC Registrar informs competent authority of receipt and screens proposal: Classifies proposal into Class 1 (fast-track) or higher (full review):

fast-track or *full-review*

Review by one specialist advisor

a: No likely impacts on neighbouring countries: full impact assessment(s)

b: Likely impacts on neighbouring countries: full impact assessment (s) and request any objections from neighbouring national advisory body

NBAC meets to consider impact assessment report(s)
Forwards recommendation to head of competent authority (see 3.2.1.5)
Head of competent authority issues formal decision to applicant

approval or *refusal*

initiation of proposal and self-monitoring

appeal may be lodged new supporting material) for re-review revised proposal may be submitted at any time (new design/techniques only)

*Proposal must contain full details of import, research, containment, field release etc., including accidental release or spillage contingency plan and self-monitoring programme where appropriate. Competent authority may also request any other reasonable contingency information, including a cash bond deposited with Government. Competent authority may also specify regular reporting requirements and/or appoint an independent monitor for the project at the applicant's expense. If proposals require additional material or peer review the competent authority shall request these and pause its timetable for proposal processing until these materials are received. The processing time should be reasonable and justifiable.

3.2.2 Research and development structures

Promotion of the safe use of biotechnology in Namibia involves the strengthening of research, development and biosafety capacities. Institutions and companies with current biotechnology research activities include:

- National Forensic Science Institute
- MAWRD Central Veterinary Laboratory
- Medical Laboratory Services
- Palmdat Namibia
- MAWRD Division of Plant Production Research

The Government of Namibia, together with the University of Namibia or Polytechnic of Namibia, should liase with heads of regional training programmes to determine a cost-effective strategy for training Namibians in biotechnology procedures, biosafety guidelines, risk assessment and risk management. Government shall liase with training programme heads to ensure effective placement of such graduates in regulatory and related government agencies. Namibia shall rationalise its investment by making maximum use of existing regional and other education and training bodies in biotechnology and biosafety, and by preparing its undergraduate students for easy entry into such programmes by means of curriculum stream options. It shall also include awareness modules for non-specialist undergraduates in fields such as trade, finance, health, agriculture and environmental management.

Government regulatory and policy agencies shall endeavour as a matter of urgency to identify and implement appropriate in-house or continuing education and training mechanisms for their existing staff and notify the Ministry of Finance of financial needs requested from Government and non-Government sources.

3.2.2.1 Risk assessment and containment of laboratory and field uses

- *Laboratory use* of biotechnology can be in any field, e.g. agriculture, the beverage industry, mining, veterinary research.
- *Field releases* are currently most likely in agriculture (e.g. genetically modified crops) or waste management (e.g. municipal or industrial use of genetically modified microorganisms for sewage or sludge treatment), but they may also occur in other fields.

- Given the potential risks to human and environmental health resulting from introduction into the environment of genetically modified organisms and foodstuffs, proposed field releases must be stringently assessed and controlled on the basis of credible and locally appropriate scientific data.

- A clear distinction must be made between viable and non-viable genetically modified organisms or products. Viable products (which can grow and reproduce, e.g. whole grain for livestock feed) are capable of fundamentally greater environmental impacts when released, and require stringent control.

- Fundamental steps in risk assessment, below, shall be followed for all biotechnology activities:

RISK (IMPACT) ASSESSMENT, CONTAINMENT MEASURES AND CLASSIFICATION FOR GMOs

Carry out risk assessment

↓

Determine appropriate containment measures

↓

Compare appropriate containment measures with containment tables (Schedule 1, EU Contained Use Regulations 2000)

↓

Do measures correspond exactly to those specified for a given containment level?

↓

Assign activity to class corresponding to containment level

↓

Notify according to class

↓

Apply full containment measures as determined by risk assessment

↓

Do measures fall between two containment levels, i.e. all specified measures at lower level apply, but one or more are requirements only at the higher level?

↓

Assign activity to class corresponding to the higher of the two containment levels

↓

Notify according to class and apply Containment measures. Notifier may seek competent authority agreement to omission of certain measures, only if justified by risk assessment.

↓

If notifier makes no application for omission of measures:

↓

Apply full containment measures specified at relevant containment level

If competent authority does not agree to omit measures:

↓

Apply full containment measures specified at relevant containment level

If competent authority agrees omit measures:

↓

Apply containment measures shown to be appropriate by risk assessment and agreed by competent authority

3.2.2.2 Laboratory containment standards

Within two years from the adoption of this policy by the Government of Namibia, all laboratories with biotechnology capacity or activities in Namibia shall have:

- implemented standards and procedures as identified by the competent authority
- identified and placed staff on biosafety training courses;
- allowed regular inspections as required by staff of the MHEVTST's National Biosafety Inspectorate in order to assess progress toward the implementation of technical guidelines.

In the interim, laboratories must implement procedures for handling, containment and disposal which are as stringent as possible with existing facilities, equipment and disposal services.

3.3 Financial implications

Biotechnology is an exceptionally expensive and specialised field of technology. If taken as an important component of a national science and technology strategy, it involves huge investment in infrastructure, equipment and specialist training. Equally, the regulation and monitoring of biotechnology is costly for governments, irrespective of their own biotechnology capacity.

Government shall provide further creative policy and financial incentives to support institutional development, through activities of the MHEVTST as the competent authority. This shall include support of independent research and independent review through informal and formal co-ordination and support mechanisms. Government, through the MHEVTST, is likely to incur initial personnel costs for the National Biosafety Inspectorate and NBAC review functions for several years. Preparation of financial scenarios is desirable to assess the point at which the National Framework will likely become financially sustainable based on application and license fees and other revenues.

Investment will become necessary to build capacity for biotechnology applications and regulation on a through training, research and advisory partnerships at regional and international level. It is essential that Namibia quickly improves its regulatory, decision-making, research and development capacity, and its level of public awareness of the issues.

3.4 Policy linkages

This national policy deals with a specialised topic. However, biotechnology is gaining increasing global importance in the fields of agriculture, public health, waste management, mining, and other areas, and thus policies in all these fields may need revisiting to determine what, if

any, amendments need to be made to take account of these global trends. Further, the important risk-assessment and regulatory implications for the safe use of biotechnology in Namibia, including border control, trade, environmental assessment and public health assessment, inspection and enforcement require detailed analysis of existing policy and practice.

Fundamentally, this policy reflects the important principles of the Namibian Constitution, including those of Article 95 (l) on the protection of biological diversity and essential ecological processes, and sustainable use of natural resources.

Important related national policies are:

- ***Namibia's Environmental Assessment Policy (January 1995)***

The policy provides detailed guidelines for environmental impact assessment procedures and administrative Structures.

- ***National Agriculture Policy (October 1995)***

The policy provides, *inter alia*, for the strengthening of agro-industrial development and complementarity between sectors; for sustainable natural resource development and food security; for improved transfer of locally and environmentally appropriate technologies to farmers through extension services; for the use of environmentally friendly practices, farm inputs and technologies; for the increase of funds for agro-ecological research, environmental monitoring, environmental extension and training; for the diversification of agricultural production in market-oriented farming systems; for research on locally adapted farming systems; and for activities relating to plant quarantine, food safety, export processing, resource management and inspection. It further recognises Namibia's fragile ecosystem and degraded natural resources as fundamental constraints to agricultural development.

Key linkages also exist with national policies on trade, industry, public health, occupational safety, border control, mining, fisheries, forestry, relations with regional structures such as SADC, and relations with international treaties and protocols. Further dialogue is needed with specialists from the competent authorities in these fields to determine the details of such linkages.

- ***National Science and Technology Policy***

Cabinet recently approved the National Policy for Science and Technology which, among other things, proposed a set of core institutions to ensure proper coordination, funding and focused research and beneficial outcome of science and technology outcomes . The National Science and Technology Policy envisaged appropriate policy and legislation on the safe and economic use of biotechnology resources. It also provides for the development of a national biotechnology framework to guide production, trade and use of our diverse biotechnological resources and to ensure that our resources and our environment provide sustainable benefits to present and future generations .

ANNEX

DEFINITIONS*

Advance informed agreement is a formal agreement between two States, or between a State and a group of States belonging to a regional economic integration organisation, to transfer any GMO or products thereof, based on information supplied by the exporting State, with the explicit understanding that the information is complete and accurate.

Adverse effect is any short- or long-term negative impact on the conservation of biological diversity (including agricultural biodiversity) or the sustainable use of its component resources, or on human or animal health.

Affected party is any party affected or likely to be affected by the transboundary transfer or release of GMOs or products thereof.

Biosafety is a term used to describe the policies and procedures necessary to ensure the safe application of modern biotechnology and any activity (handling, transfer, use) associated with GMOs, which may adversely affect the conservation and sustainable use of biodiversity and biological resources.

Biotechnology (modern biotechnology) is the use of genetic modification techniques, including cell and tissue culture methods, to produce novel traits not present in wild organisms or to develop novel diagnostic or therapeutic materials.

Competent authority is any governmental or intergovernmental authority with sufficient relevant scientific capacity, designated by a Party to be regulate biotechnology and biosafety, to issue and receive notification and make advance informed agreements of transboundary transfers or releases of GMOs or products thereof, and to issue or withdraw approval for the handling and use of GMOs.

Contained use **or** ***containment*** refers to any limited experimental, non-commercial activity involving organisms, which prevents contact between them and the environment (including humans) by physical, chemical and/or biological barriers.

Convention is the Convention on Biological Diversity, adopted in Rio de Janeiro on 5 June 1992.

Deliberate release is any intentional introduction into the environment of GMOs or products thereof, including trial release.

GMO (genetically modified organism) is any living organism or part thereof which is capable of regenerating itself on its own or in the body or cell of another organism, and whose genetic

*The definitions are not final and may be adjusted to internationally agreed ones.

material has been modified by modern biotechnology in a way not occurring naturally by mating or natural recombination. The definition includes any living material or part thereof, which had been a fossil but has been resuscitated through modern biotechnology.

Illegal traffic means any transboundary movement or transfer of GMOs or products thereof without official notification to, or advance informed agreement of, all States concerned; or with such agreement obtained through falsification, misrepresentation, incomplete reporting or fraud; or with such agreement which does not conform to submitted documents or which results in the deliberate release of GMOs in contravention of the International Protocol on Biosafety (still in negotiation during 1999).

Party means a Party to the International Protocol on Biosafety (until this Protocol is agreed, it refers by default to a Party to the Convention on Biological Diversity).

Party to the CBD means a Party to the Convention on Biological Diversity.

Party of origin is the State from whose jurisdiction a transboundary release or transfer of a GMO or products thereof has taken place, or is envisaged to take place

Precautionary approach means that the lack of scientific certainty linking a negative situation to a likely cause shall not be used as a reason to delay or avoid remedial action through cessation or minimisation of the presumed cause.

Products of genetically modified organisms include viable genetic material or non-viable processed products of GMOs.

Risk assessment is the use of scientific and other appropriate methods to identify and characterise the nature, likelihood of occurrence, and potential magnitude of any hazards, with due regard to the precautionary principle.

Risk management means the framework of activities and decisions involved in containing and reducing the risks from the use of biotechnology.

Transboundary movement is any movement of GMOs, intentional or unintentional, and by any means including gene transfer, across one or more national boundaries.

Transboundary release is any use of, or activity or incident involving a GMO other than contained use, across one or more national boundaries.

Trial release is the deliberate release of GMOs into the environment in the open under conditions, which restrict, through physical, chemical and/or biological means, the dispersal or survival of such organisms in the broader environment.

Unintended release is the accidental entry of GMOs or products thereof into the natural environment or market without prior approved intent or consent.

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