Namibian Country Study

on

Biosafety and Biotechnology

Summary

Presented at:
The UNEP/GEF Pilot Project National Workshop
"Developing a National Biosafety Framework"
3 - 4 February 1999
Windhoek, Namibia

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Contents

Preamble................................................................................................................. 1
Acronyms and abbreviations.................................................................................. 2
Glossary of terms.................................................................................................... 5
Chapter 1 Introduction............................................................................................ 11
Chapter 2 Brief overview of Namibia, its economy and its society...................... 14
Chapter 3 Development goals.................................................................................. 24
Chapter 4 Biotechnology in perspective............................................................... 26
Chapter 5 Regional status of biotechnology......................................................... 34
Chapter 6 Local capacity to deal with biotechnology.......................................... 36
Chapter 7 Conclusions......................................................................................... 42
Chapter 8 Recommendations.................................................................................. 47
References and suggested further reading......................................................... 67
Preamble

A country study on biosafety and biotechnology has been undertaken by a consultant on behalf of the Namibian Biotechnology Alliance (NABA) and was funded by the United Nations Environment Programme Global Environment Facility. A comprehensive report and draft technical guidelines were handed to NABA. The purpose of this summary is to give the participants of this workshop a synopsis of the approach to and findings of the country study and the resultant recommendations for reference during the discussions.

The purpose of this study was to establish
- what biotechnology applications are currently used or would potentially used in Namibia;
- what regulatory mechanisms for such use are in place;
- who the relevant role players are and potentially will be in future;
- and to furnish recommendations regarding the development of a National Biosafety Framework for Namibia.

It was attempted to define the macro environment, which includes facts relating to Namibia's environment, population and economy, in which the regulatory framework would have to function.

It was attempted to achieve the broadest possible input, to determine the local capacity to deal with biotechnology per se and the regulation thereof, taking into account that decisions have to be based on scientific fact, relevant in the Namibian context and also considering global trends in the biotechnology industry.

The recommendations made include the structure and procedure of the national regulatory body, technical guidelines for work with genetically modified organisms, risk assessment and management, as well as a legal framework within which this biosafety framework can function.

The discussions at this workshop will aid the development of a Namibian National Biosafety Framework, by broadening the basis of input and viewing the issue from different perspectives.

It is hoped that the groundwork laid down and the discussions at this meeting achieve the aim of developing a fair, appropriate and internationally acceptable Namibian National Biosafety Framework.

*Note: The references quoted are supplied with the full text of the Namibian Country Study on Biotechnology and Biosafety report to NABA.*

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Hartmann, A.M.: *Summary: Namibian Country Study on Biosafety and Biotechnology*

*Developing a National Biosafety Framework*

*UNEP-GEF Workshop, Windhoek, 3-4 February 1999*
### Acronyms and Abbreviations

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>BINAS</td>
<td>Biosafety Information Network and Advisory Service (of the United Nations Industrial Development Organisation)</td>
</tr>
<tr>
<td>BSE</td>
<td>Bovine spongiform encephalopathy</td>
</tr>
<tr>
<td>CBD</td>
<td>Convention on Biological Diversity</td>
</tr>
<tr>
<td>CBPP</td>
<td>Contagious Bovine pleuropneumonia</td>
</tr>
<tr>
<td>COP</td>
<td>Conference of the Parties (to the CBD)</td>
</tr>
<tr>
<td>CSD</td>
<td>Commission for Sustainable Development</td>
</tr>
<tr>
<td>CVL</td>
<td>Central Veterinary Laboratory (MAWRD)</td>
</tr>
<tr>
<td>DEA</td>
<td>Directorate Environmental Affairs (MET)</td>
</tr>
<tr>
<td>DNA</td>
<td>Deoxyribonucleic acid</td>
</tr>
<tr>
<td>DVS</td>
<td>Directorate of Veterinary Services (MAWRD)</td>
</tr>
<tr>
<td>EC</td>
<td>European Commission</td>
</tr>
<tr>
<td>EEZ</td>
<td>Exclusive economic zone</td>
</tr>
<tr>
<td>EIA</td>
<td>Environmental impact assessment</td>
</tr>
<tr>
<td>ESD</td>
<td>Environmentally sustainable development</td>
</tr>
<tr>
<td>FAO</td>
<td>Food and Agriculture Organisation of the United Nations</td>
</tr>
<tr>
<td>FMD</td>
<td>Foot-and-Mouth disease</td>
</tr>
<tr>
<td>GEF</td>
<td>Global environment facility</td>
</tr>
<tr>
<td>GEM</td>
<td>Genetically engineered micro-organism</td>
</tr>
<tr>
<td>GILSP</td>
<td>Good industrial large-scale practice</td>
</tr>
<tr>
<td>GMAC</td>
<td>Genetic Manipulation Advisory Committee</td>
</tr>
<tr>
<td>GMM</td>
<td>Genetically modified micro-organism</td>
</tr>
<tr>
<td>GMO</td>
<td>Genetically modified organism</td>
</tr>
<tr>
<td>IACSD</td>
<td>Inter-Agency Committee on Sustainable Development</td>
</tr>
<tr>
<td>Abbreviation</td>
<td>Full Form</td>
</tr>
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<td>--------------</td>
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</tr>
<tr>
<td>IBC</td>
<td>Institutional biosafety committee</td>
</tr>
<tr>
<td>LMO</td>
<td>Living modified organism</td>
</tr>
<tr>
<td>MAWRD</td>
<td>Ministry of Agriculture, Water and Rural Development</td>
</tr>
<tr>
<td>MBEC</td>
<td>Ministry of Basic Education and Culture</td>
</tr>
<tr>
<td>Meatco</td>
<td>Meat Corporation of Namibia</td>
</tr>
<tr>
<td>MET</td>
<td>Ministry of Environment and Tourism</td>
</tr>
<tr>
<td>MFMR</td>
<td>Ministry of Fisheries and Marine Resources</td>
</tr>
<tr>
<td>MHEVTST</td>
<td>Ministry of Higher Education, Vocational Training, Science and Technology</td>
</tr>
<tr>
<td>MHSS</td>
<td>Ministry of Health and Social Services</td>
</tr>
<tr>
<td>MLHRD</td>
<td>Ministry of Labour and Human Resource Development</td>
</tr>
<tr>
<td>NABA</td>
<td>Namibian Biotechnology Alliance</td>
</tr>
<tr>
<td>NAU</td>
<td>Namibian Agricultural Union</td>
</tr>
<tr>
<td>NBAC</td>
<td>Namibian Biotechnology Advisory Council</td>
</tr>
<tr>
<td>NDP1</td>
<td>First National Development Plan</td>
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<tr>
<td>NGO</td>
<td>Non-governmental organisation</td>
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<tr>
<td>NNFU</td>
<td>Namibian National Farmers Union</td>
</tr>
<tr>
<td>OECD</td>
<td>Organisation for Economic Co-operation and Development</td>
</tr>
<tr>
<td>OIE</td>
<td>Office International des Epizooties (World Organisation for Animal Health)</td>
</tr>
<tr>
<td>ONT</td>
<td>Organism with novel traits</td>
</tr>
<tr>
<td>OTA</td>
<td>Office of Technology Assessment of the U.S. Congress</td>
</tr>
<tr>
<td>PCR</td>
<td>Polymerase chain reaction</td>
</tr>
<tr>
<td>rDNA</td>
<td>Recombinant DNA</td>
</tr>
<tr>
<td>RNA</td>
<td>Ribonucleic acid</td>
</tr>
<tr>
<td>SACU</td>
<td>Southern African Customs Union</td>
</tr>
<tr>
<td>SADC</td>
<td>Southern African Development Community</td>
</tr>
<tr>
<td>UNAM</td>
<td>University of Namibia</td>
</tr>
<tr>
<td>UNCED</td>
<td>United Nations Conference on the Environment and Development</td>
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</table>

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*Developing a National Biosafety Framework*

*CNEP/GEF Workshop, Windhoek, 3-4 February 1999*
UNEP  United Nations Environment Programme
UNIDO  United Nations Industrial Development Organisation
VAN  Veterinary Association of Namibia
WHO  World Health Organisation
WTO  World Trade Organisation
# Glossary of Terms

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aerosol</td>
<td>Suspension in air of finely dispersed solids or liquids.</td>
</tr>
<tr>
<td>Agrobacterium tumefaciens</td>
<td>A bacterium that infects plants and contains a plasmid that can be used to introduce foreign DNA into plant cells.</td>
</tr>
<tr>
<td>Amphotropic retrovirus</td>
<td>A retrovirus that will grow in the cells from which it was isolated and also in cells from a wide range of other species.</td>
</tr>
<tr>
<td>Amplify</td>
<td>To increase the number of copies of a gene or DNA sequence.</td>
</tr>
<tr>
<td>Autoclave</td>
<td>A device in which materials are sterilised using steam under high pressure.</td>
</tr>
<tr>
<td>Bacterium</td>
<td>A single-celled prokaryotic organism.</td>
</tr>
<tr>
<td>Bacteriophage</td>
<td>A virus that infects bacteria; also called phage.</td>
</tr>
<tr>
<td>Batch record</td>
<td>The record kept for each batch or run of a project which includes details of processing, maintenance, accidents, and disposal.</td>
</tr>
<tr>
<td>Baculovirus</td>
<td>A group of viruses that infect insects and can be used as vectors to produce foreign proteins in insect cells.</td>
</tr>
<tr>
<td>Biological safety cabinet</td>
<td>Specially constructed cabinets that are designed to protect workers and the environment from dangerous agents, especially bacteria and viruses.</td>
</tr>
<tr>
<td>Biosafety cabinet</td>
<td></td>
</tr>
<tr>
<td>Biotechnology</td>
<td>Biotechnology can be defined as technology/techniques involving the integrated application of biological sciences such as genetics, molecular biology, microbiology and engineering to produce goods and/or services from living organisms or parts or products thereof.</td>
</tr>
<tr>
<td>Cell</td>
<td>The smallest structural unit of living organisms that is able to grow and reproduce independently.</td>
</tr>
<tr>
<td>Chromosome</td>
<td>A structure in the cell, consisting of DNA and proteins, that carries the organism’s genes.</td>
</tr>
<tr>
<td>Clone</td>
<td>As a noun: a group of genes, cells, or organisms derived from a common ancestor and genetically identical. As a verb: to generate replicas of DNA sequences or whole cells using genetic manipulation techniques.</td>
</tr>
<tr>
<td>Conjugative plasmid</td>
<td>A plasmid that codes for its own transfer between bacterial cells by the process of conjugation (mating).</td>
</tr>
<tr>
<td>Construct</td>
<td>As a noun: genetically manipulated DNA.</td>
</tr>
</tbody>
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Containment

Prevention of the spread of genetically manipulated organisms outside the laboratory. Physical containment is accomplished by the use of special procedures and facilities. Biological containment is accomplished by the use of particular strains of the organism that have a reduced ability to survive or reproduce in the open environment.

Containment level

The degree of physical containment provided by a laboratory, which depends on the design of the facility, the equipment installed, and the procedures used. Physical containment levels are numbered from one to three, three being the highest level.

Decontamination

Physical or chemical process that kills or removes unwanted infectious agents (does not necessarily result in sterility).

defective virus

A virus that is unable to reproduce in its host without the presence of another (helper) virus.

DNA

Deoxyribonucleic acid, the molecule that carries the genetic information for most organisms; consists of four bases and a sugarphosphate backbone.

Donor

The organism or cell from which DNA is derived for insertion into another organism (the host).

ecotropic retrovirus

A retrovirus that will grow in cells of the species from which it was isolated, but to a very limited or undetectable level in cells of other species.

Effluent

Liquid (or gaseous) industrial waste.

embryo-rescue

The process in plant breeding whereby tissue from young embryo plants is excised and propagated in vitro for subsequent growth as differentiated plants.

*Escherichia coli* (E. coli)

A bacterium that inhabits the intestinal tract of humans and other animals.

*Escherichia coli* K12

A strain of *E. coli* that has been maintained in culture in laboratories for many years. It has lost the ability to colonise the intestinal tract of humans and animals, is well-characterised genetically, and is often used for molecular cloning work.

*Escherichia coli* B

Another well-characterised laboratory strain of *E. coli*.

Eukaryotic

Belonging to the group of organisms whose cells contain a true nucleus. Eukaryotic organisms include animals, plants, and fungi.

Expression

Manifestation of a characteristic that is specified by a gene; often used to mean the production of a protein by a gene that has been inserted into a host organism.

Fungi

Nonphotosynthetic eukaryotic organisms, including moulds, that feed on organic matter.
Fusion  
joining of the cell membranes of two cells to create a daughter cell that contains the genetic material from both parent cells.

GAP  
Good agricultural principles.

Gamete  
A reproductive (egg or sperm) cell.

Gene  
A hereditary unit of nucleic acid that specifies the structure of a protein or RNA molecule.

gene therapy  
The replacement of a defective gene in a person or other animal suffering from a genetic disease.

genetic engineering  
See genetic manipulation.

genetic manipulation  
A technology used to alter the genetic material of living cells or organisms in order to make them capable of producing new substances or performing new functions.

Genome  
The total genetic complement of a given organism.

Genotype  
The genetic makeup of an organism, as distinguished from its physical appearance (the phenotype).

germline cells  
Gametes and the cells from which they are derived. The genetic material of germline cells, unlike that of somatic cells, can be passed to succeeding generations.

GMO  
Genetically modified organism, where the genetic make up of the organism has been artificially altered.

growth factor  
A protein that stimulates cell division when it binds to its specific cell-surface receptor.

helper virus  
A virus that, when used to infect cells already infected by a defective virus, enables the latter to multiply by supplying something the defective virus lacks.

HEPA filter  
High efficiency particulate air filter with trapping efficiency greater than 99.99 percent for particles of 0.3 micrometers in diameter.

HIV  
Human immunodeficiency virus (a retrovirus).

Host  
A cell or organism into which foreign DNA is introduced to enable production of proteins or further quantities of the DNA.

host range  
For a virus, the range of species that can be infected by that virus.

host-vector system  
Combination of host and the vector used for introducing foreign DNA into the host.

Hybridoma  
A hybrid cell used in production of monoclonal antibodies that is produced by fusing an antibody-producing cell (B lymphocyte) with a tumour cell.
<table>
<thead>
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</tr>
</thead>
<tbody>
<tr>
<td>in vitro</td>
<td>Literally in glass; performed in a test tube or other laboratory apparatus.</td>
</tr>
<tr>
<td>in vivo</td>
<td>In a living organism.</td>
</tr>
<tr>
<td>LMO</td>
<td>Living modified organism; a living organism whose genetic composition has been artificially altered to express characteristics that differ from the original parent organism</td>
</tr>
<tr>
<td>Micro-organism</td>
<td>An organism that can be seen only with the aid of a microscope.</td>
</tr>
<tr>
<td>monoclonal antibody</td>
<td>An antibody that is derived from a single clone of hybridoma cells and recognises only one antigenic site.</td>
</tr>
<tr>
<td>Oncogene</td>
<td>An activated (modified) cellular gene that causes normal cells to become cancerous.</td>
</tr>
<tr>
<td>Oocyte</td>
<td>A cell that divides to form the female reproductive cell.</td>
</tr>
<tr>
<td>Packaging</td>
<td>In the process of virus replication, the assembly of the components of the virus to form the complete virus particle.</td>
</tr>
<tr>
<td>Pathogen</td>
<td>An organism that causes disease.</td>
</tr>
<tr>
<td>PCR</td>
<td>See polymerase chain reaction.</td>
</tr>
<tr>
<td>Phage</td>
<td>See bacteriophage.</td>
</tr>
<tr>
<td>Phenotype</td>
<td>The observable properties of an organism as distinguished from its genetic makeup (the genotype).</td>
</tr>
<tr>
<td>planned release</td>
<td>Intentional release of a genetically modified organism into the open environment.</td>
</tr>
<tr>
<td>Plasmid</td>
<td>A small, self-replicating molecule of DNA that contains a specific origin of replication. Plasmids are often used as cloning vectors.</td>
</tr>
<tr>
<td>plasmid mobility</td>
<td>The rate at which the vector-insert could subsequently be transferred from the original recipient.</td>
</tr>
<tr>
<td>polymerase chain reaction</td>
<td>A technique for generating in vitro an increased quantity of a target segment of DNA.</td>
</tr>
<tr>
<td>Prion</td>
<td>An infectious agent of unknown etiology that causes spongiform encephalopathies in humans and animals.</td>
</tr>
<tr>
<td>Prokaryotic</td>
<td>Belonging to the group of microorganisms whose DNA is not enclosed within a nuclear membrane.</td>
</tr>
<tr>
<td>Promoter</td>
<td>A DNA sequence, located in front of a gene, that controls expression of the gene. It is the sequence to which RNA polymerase binds to initiate transcription.</td>
</tr>
</tbody>
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<tbody>
<tr>
<td>Protein</td>
<td>A molecule composed of amino acids.</td>
</tr>
<tr>
<td>Protoplast</td>
<td>A plant or bacterial cell that has had the outer cell wall removed.</td>
</tr>
<tr>
<td>Receptor</td>
<td>Cell-surface protein to which molecules, such as hormones and growth factors, bind to exert their effects on the cell, or to which viruses bind to gain entry to the cell.</td>
</tr>
<tr>
<td>Recombinant</td>
<td>Organisms, cells, viruses, and the like that contain recombinant DNA.</td>
</tr>
<tr>
<td>recombinant DNA</td>
<td>DNA formed by joining in vitro segments of DNA from different organisms.</td>
</tr>
<tr>
<td>Recombination</td>
<td>The occurrence or production of progeny with combinations of genes other than those that occurred in the parents.</td>
</tr>
<tr>
<td>Replication</td>
<td>Reproduction.</td>
</tr>
<tr>
<td>resistance marker</td>
<td>A gene that confers antibiotic resistance to the recipient micro-organism.</td>
</tr>
<tr>
<td>retroviral vector</td>
<td>A retrovirus that is used to introduce foreign DNA into animal cells, usually by replacing part of the viral genome with the foreign DNA of interest.</td>
</tr>
<tr>
<td>Retrovirus</td>
<td>A virus that uses the enzyme reverse transcriptase to copy its RNA genome into DNA, which then integrates into the host cell genome.</td>
</tr>
<tr>
<td>RNA</td>
<td>Ribonucleic acid, a molecule similar to DNA whose functions include decoding the instructions for protein synthesis that are carried by the genes, comprises the genetic material of some viruses.</td>
</tr>
<tr>
<td>Sharps</td>
<td>Sharp laboratory items, such as syringe needles, scalpels and razor blades, and broken glass.</td>
</tr>
<tr>
<td>shotgun cloning</td>
<td>the production of a large random collection of cloned fragments of the DNA of an organism from which genes of interest can later be selected.</td>
</tr>
<tr>
<td>somatic cell</td>
<td>Any cell of a multicellular organism other than germline cells.</td>
</tr>
<tr>
<td>SOP</td>
<td>Standard operating procedure.</td>
</tr>
<tr>
<td>Sterilisation</td>
<td>Act or process that kills or removes all infectious agents; applied particularly to bacteria and moulds, their spores, and viruses.</td>
</tr>
<tr>
<td>Taxonomy</td>
<td>The study of the classification of living things.</td>
</tr>
<tr>
<td>tissue culture</td>
<td>In vitro growth of tissue cells in nutrient medium.</td>
</tr>
<tr>
<td>Toxin</td>
<td>A poisonous substance, produced mainly by micro-organisms but also by some fungi, plants, and animals.</td>
</tr>
</tbody>
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Hartmann, A.M.; Summary: Namibian Country Study on Biosafety and Biotechnology

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<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>transgenic (organism)</td>
<td>An organism whose cells, including the germline cells, contain foreign DNA; transgenic animals are produced by the insertion of the foreign DNA into the newly fertilised egg or embryo.</td>
</tr>
<tr>
<td>tumour suppressor gene or anti-oncogene</td>
<td>A gene that encodes a protein thought to be necessary for the controlled growth of normal cells. When the gene is functionary inactivated by either deletion or mutation, the cell exhibits unregulated growth resulting in neoplasia.</td>
</tr>
<tr>
<td>Vector</td>
<td>A self-replicating agent (for example, a plasmid or virus) used to transfer foreign DNA into a host cell.</td>
</tr>
<tr>
<td>Viroid</td>
<td>A disease-causing agent of plants that is smaller than a virus and consists of a naked RNA molecule.</td>
</tr>
<tr>
<td>Virulence</td>
<td>Ability of an organism to cause disease.</td>
</tr>
<tr>
<td>Virus</td>
<td>A sub-microscopic infectious particle, containing genetic material (DNA or RNA) and protein, which can replicate only within the cell of an organism (plant, animal, or bacteria).</td>
</tr>
<tr>
<td>xenotropic retrovirus</td>
<td>A retrovirus that is endogenous to a species but cannot replicate well in that species, generally because of a receptor block. Xenotropic retroviruses tend to have a wide range for replication in cells of heterologous species.</td>
</tr>
<tr>
<td>Zygote</td>
<td>The cell produced by the union of the male and female gametes.</td>
</tr>
</tbody>
</table>
Chapter 1  Introduction

"Sustainable development is development that meets the needs of the present generation without compromising the ability of future generations to meet their own needs" (5)

The intense demands by the ever expanding world population on non-renewable resources and the pressure on renewable resources through mismanagement, have led to a concerted global effort to halt, or, at least slow, the current degradation of our planet. This reached a focus with the United Nations Conference on Environment and Development (Rio de Janeiro, June 1992).

This Conference produced the Convention on Biological Diversity, which effectively is an international set of guidelines for the management of resources, with the aim to use the biological diversity of the earth sustainably for the benefit of present and future generations. (6)

Namibia is a signatory to the Convention, and the Namibian Parliament ratified this decision on the 16th March 1997. This commendable commitment by the Namibian Government to the sustainable use of natural resources as decided upon by the signatories to the convention, places a number of responsibilities on the Namibian Government with regard to the regulation of the use of modern biotechnology.

The products of modern biotechnology have become a resource, which is increasingly relied upon to meet the demands for food, shelter and health by the expanding world population (29). However, it does not offer solutions to all problems and is most certainly not without a number of serious risks. The development and commercialization of modern biotechnology has become a major industry worldwide. The long term impact of some of these technologies, however, is often not fully understood prior to large scale use.

Namibia’s Constitution and the National Development Plans and Policies are virtually unique with regard to the elements specific to the protection of the environment. It is imperative that the political will to continue on this road remains, even under perceived economic and political pressure to employ high technology prematurely to address shortcomings in the provision of health, food and shelter. After all, Namibians are those affected, should some of these technologies fail, or, have long term detrimental effects.

It is thus of the utmost importance that decisions with regard to these technologies are based on facts and credible scientific evaluation.

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The potential of selective, carefully planned use of this modern technology for Namibia lies primarily in the lessening of the impact of our growing population on finite and already over exploited natural resources. However, it can at best be considered a tool to help sustain the population and their development, while the root problems underlying environmental degradation and poverty have to be pro-actively addressed.

For the development of a National Biosafety Framework it is essential to adopt a well balanced holistic approach. Neither preservationist over regulation and a development-at-all-cost attitude toward these emerging technologies are conducive to sustainable development. Careful risk-benefit and cost-benefit evaluation should be undertaken, taking into consideration particular geographic, climatic, environmental and socio-economic facts relevant to Namibia and the proposed use of technology.

To determine the relevance and feasibility of new technologies being introduced it would be wise to evaluate the state of development of the country. For many, the state of development is merely measured by the state of the national economy. The inaptness of this approach has led to the formulation of a new concept of evaluating the state of development considering primarily the state of human wellbeing rather than the state of the national economy as defined in the Cocoyoc Declaration (Mexico, 1974) :[27]

"Our first concern is to redefine the whole purpose of development. This should not be to develop things, but to develop man. Human beings have basic needs: food, shelter, clothing, health, education. Any process of growth that does not lead to their fulfillment - or even worse, disrupts them - is a travesty of the idea of development."

The world wide trend towards more use of biotechnology applications in development is a reality that Namibia has to become equipped to deal with sensibly. However, further development is not only dependent on high technology. If the country allows itself to become dependent on high technology for the purpose of image, while disregarding its limitations and conventional means of improved productivity, economic dependence on the industrialised nations will be perpetuated. It would thus be unwise not to consider conventional alternatives, which in the Namibian context could be at least as effective, less costly and most certainly easier to manage.

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This study would fail in its purpose if it did not consider the economic, social and political perspectives of development planning and the appraisal of the plan did not meet the following prerequisites:

- internal consistency
- locational suitability
- conformity to standards and principles
- problem solving
- feasibility
- flexibility and open-endedness.

The developing world has a long history of development planning, that did not achieve the development aims. This traditional approach to planning often failed for the following reasons: (24)

- too much emphasis on the plan and not enough on its implementation
- overemphasis on the medium term, without consideration of the short term needs and long term effects
- excessive rigidity of plans, not allowing for changes in a dynamic system such as development
- differences in perspective and inadequate communication between politicians, planners and administrators

Like many developing countries, Namibia does not have the resources to duplicate existing sub-regional, regional and global structures to safely use these modern technologies. Networks of co-operation and collaboration exist on these levels and should be employed. However, decision making will most definitely have to be Namibian based.

It must be a priority to develop Namibian institutional and human resource capacity on the short term to at least a level, where Namibians can safely decide to allow or refer elsewhere for decision making support.

This study attempts to place the Namibian situation into perspective with regard to its people's needs, aspirations and limitations. It further aims to identify the needs to be addressed, critically analyse these, and furnish recommendations for achieving the goal of a responsible and internationally acceptable Biosafety Framework, in order to safely harness the potentials offered by modern technologies.

The management of developed world technologies in the developing world has to be of developed world standards in order to be safe, beneficial and non-exploitative.

Hartmann, A.M.; Summary: Namibian Country Study on Biosafety and Biotechnology

Developing a National Biosafety Framework
UNEP/GEF Workshop, Windhoek, 3-4 February 1999
Chapter 2  Brief overview of Namibia, its economy and its society

The Republic of Namibia, a multi party democratic state, gained its independence on 21 March 1990.

Namibia is situated on the south west coast of Africa bordered by the Atlantic Ocean in the west, Angola and Zambia in the north, Botswana in the east and South Africa in the south.

The topography is characterised by a narrow coastal plain with a steep gradient towards a flat inland plateau. Namibia is an arid country with approximately 92% of its total surface area classified as semi-arid or arid and a hyper-arid zone along the Namib Desert in the west.\(^{(22)}\)

Namibia has a few perennial rivers along its northern border and one along the southern border, none of which have their headwaters within the boundaries of the country. Rainfall is extremely variable and unpredictable, ranging from less than 50mm to more than 700mm on average annually.\(^{(22)}\)

Precipitation often occurs in the form of thunderstorms. Prevailing degradation of rangeland and the topography result in a high rate of run off and low levels of ground infiltration.\(^{(34,36)}\) It is estimated that 83% of total rainfall evaporates shortly after precipitation. Of the remaining amount, 14% is used by plants for evapotranspiration, 2% enters soil drainage systems where a proportion is available for utilisation from surface facilities and only 1% recharges the ground water resources.\(^{(22)}\)

Namibia is currently dependent on three major types of water source. Approximately 23% of requirements are supplied by the major perennial rivers along the borders in the north and south, 57% from ground water resources and only 20% from a number of surface reservoirs. The capacity of these surface reservoirs to function as a reliable supply varies with the unpredictable recharge from flooding ephemeral rivers.\(^{(22)}\)

The nature of the precipitation, the gradient and resultant run-off and floods in the ephemeral rivers fed by these drainage systems can potentially disseminate hazardous material, such as plant seeds or infective material, originating in the high lying interior, over long distances. This could be, in the case of the western ephemeral rivers into the unique and fragile environment of the Namib desert, and on rare occasions even reach the coast and ocean. In the case of the eastern ephemeral rivers it could cause potential trans-boundary damage to the unique ecosystem of the Okavango Delta.
Rural water supply is mostly dependent on ground water as only source. Per capita water consumption varies from relatively low (unmetered) in the rural to unsustainably high in the urban populations. Without proper management of the limited water resources, overexploitation is likely. Future development must consider the limitations set by limited resource. The projected growth in urban populations necessitates urgent changes in water use patterns and improved efficiency of use. [36]

The population of Namibia is presently estimated to be approximately 1.65 -1.7 million people. Namibia is one of the least densely populated countries in the world with an average of about 1.9 people per square km, but up to 100 people per square km in some areas.

The majority of Namibia's population lives in the northern communal areas, which hold approximately 60% of the total population. Population is concentrated especially in the four central regions in the North, which support about two thirds of the total population of the northern communal areas, or almost half of the total population in Namibia. In the Cuvelai drainage area about 28% of the entire Namibian population lives on less than 1% of Namibia's land. [23]

Most of the population of Namibia is rural, and depends heavily on natural resources for subsistence. The only major urban centre is Windhoek, with a human population of approximately 200 000; fewer than ten other towns have populations in excess of 10,000, and there are only 18 towns of over 5,000 people. Urbanisation has been a marked recent trend at >5%, [6].

The population growth rate is estimated to be between 3.1% and 3.3%. At this rate the total population can be expected to double in about 22 years, to approximately 3.5 million by the year 2020. The total fertility rate (average number of live births to women of reproductive age) is approximately 5.4. This high fertility and growth rate results in 42% of the population being under age 15. [9]

Poverty, both in relative and absolute terms, is still a serious problem in Namibia. Relative poverty reflects the highly skewed distribution of income and consumption whereby the richest 1% of the population consume as much as the poorest 50%. In absolute terms, 47% of households can be categorised as poor and 13% of these can be classified as severely poor. [9]

Unemployment stands at approximately 20%. The level of unemployment is much higher among the urban than the rural population - 25.8% and 14.6% respectively. Of the unemployed, 21% have no schooling, 39% only junior schooling and another 39% have junior secondary schooling. Only 1% of the unemployed have senior secondary or higher education. [9]
The diseases HIV/AIDS, tuberculosis and malaria are the main concerns of health authorities and could cause major impact on the country's economy. The relatively high incidence of malnutrition is a matter of concern. 

Because of the generally arid and variable climate, Namibia has a very limited potential for reliable crop production, and extensive livestock production is thus the major agricultural activity. Approximately 85% of Namibia's surface area is utilised for various sectors of agriculture or related activities.

The agricultural sector is also one of the key contributors to the Gross Domestic Product. Agriculture currently contributes more than 6.5% to overall economic activity. The sector is the main source of employment and livelihoods for the population, with an about 70% dependent to a greater or lesser extent upon it. The majority of the population will continue to rely upon the agricultural sector for their livelihoods.

Of the approximately 85% of the country's surface area used for various forms of agriculture, 45% is privately owned farmland and 40% communal farmland. The changes that have taken place in agricultural production systems and land tenure during this century, have had a serious effect on the environment.

Localised overutilisation and inappropriate use of resources has taken place in the communal as well as commercial farmland areas. As a result, desertification and bush encroachment have become major concerns, with a large percentage of range land having lost much of its production potential. Although the outcome of inappropriate land use in the communal and commercial farmland is similar, they have dissimilar origins.

Agriculture in general makes only a small and declining contribution to average communal tenure area household income, ranging from 16% in the central northern communal area to 34% in Caprivi. The remainder is obtained from other sources, such as pensions and formal sector employment. The availability of cash income is more likely to determine household food security than agricultural production.

In most of the communal areas, livestock ownership consists of a few large herd owners, and many with few animals. Up to 90% of households in some areas, do not own enough animals to earn a livelihood from livestock production alone.

Although differences exist between regions, crop production takes place on a subsistence basis in the rural areas. The main crop is pearl millet, but maize is also cultivated on a smaller scale. Rural women are mainly responsible for the subsistence mono culture crop cultivation.
Modern methods of improving yields are hardly ever employed. Small scale irrigation takes place in many areas, utilising bore hole water. Such a system is unlikely to be sustainable. \(^{34}\)

As a result of the degradation of the resource base and the rapidly growing population, current agricultural production is inadequate to meet basic food needs among many northern households. Food insecurity is a serious concern among much of the rural, and even urban population.

Various crops are cultivated in a limited area, particularly dryland cropping in the Grootfontein-Otavi-Tsumeb triangle, and under irrigation along the Orange, Okavango and Zambezi rivers and in the Hardap and Naute areas.

The entire western coastal zone is true desert, with a mean annual rainfall of less than 100 mm per year, and mean annual evaporation about thirty times as great. Rainfall increases from the south west to the north east, ranging from less than 50 mm to 700 mm. Only 8% of the country receives more than 500 mm per year, the minimum considered necessary for dryland crop production.

The harsh climatic conditions of low rainfall and very high surface water evaporation rates, which exceed the rainfall by between 420% in the northern regions and 1750% in the south eastern regions, severely limit the levels of productivity that can be achieved in agricultural crop production. \(^{22}\)

The productivity of subsistence crop production, which is primarily pearl millet, is generally very low, with yields of between 0.35 t/ha (1991) and 0.15 t/ha (1998). The yields of white maize in the commercial and communal sectors combined, range from 1.23 t/ha (1991) to 0.55 t/ha (1998) with the commercial area being slightly more productive at 0.72 t/ha in 1998. \(^{9}\)

The reluctance and economic constraints to employ conventional methods of improving productivity, apart from the environmental factors, contribute to these low production rates.

The result of such low productivity is that Namibia retains the status of being a net importer of basic foodstuffs, leading to the perpetuation of dependence on costly imports of staple foods like maize and wheat, and is cause for concern.

Other crops, fruit and vegetables are produced at a much smaller scale throughout the country on dry land and under irrigation.

These include cotton, groundnuts, sunflower, cow peas, citrus, mango's, dates, table grapes and a variety of vegetables.

There is an increasing export market of table grapes to particularly Europe, where the product has the competitive advantage of the timing of availability.

The main production areas are concentrated in the Tsumeb-Grootfontein-Otavi triangle, along the Okavango and Orange rivers and in the vicinity of the Hardap and Naute dams, where irrigation is feasible.
The Namibian Agronomic Board, a statutory Body, is the official marketing agency for controlled agronomic products. Agronomic producers, who produce more than 5 tonnes of controlled agronomic products (maize, wheat and sunflower seed) annually, as well as processors of these products, have to register with the board. Currently there are 314 registered producers and 34 registered processors. (1)

It is estimated that there are 2.05 million cattle, 2.42 million sheep and 1.82 million goats in the country’s herds. (7) The level of productivity varies with prevalent climatic conditions. However, a high percentage of production units in the communal and commercial sectors operate at extremely low productivity levels irrespective of climatic impact.

The economic output of commercial livestock production has increased, though not at the same rate as that of communal livestock production and crop production. This is mainly due to upward changes in commodity prices in the communal sector and emergency sales during drought conditions, and not due to improved productivity. (3)

Namibia is a net exporter of livestock and processed beef. Strict regulations regarding drug and chemical residues and control of the livestock disease situation, have allowed preferential marketing of beef to Europe under the Lome’ Agreement. The main importer of livestock and products remains South Africa.

There has been a downward tendency in the profitability of commercial livestock production systems. One major contributing factor to the 30% decrease in profitability over the past quarter century is the increase in input costs, while the produce price stagnated. This led in many areas to the overexploitation of natural resources, which in turn accelerated land degradation, including bush encroachment, which has seriously affected the livestock carrying capacity and profitability of most of the commercial farmlands. (33)

Thus livestock production is under severe economic pressure through rapidly increasing level of input costs, decreasing renewable resources and stagnating produce prices. Serious attention will have to be given to means of raising the productivity in livestock production systems.

Supporting services to the livestock industry are found both in the public and private sector.

The Ministry of Agriculture, Water and Rural Development, maintains a broad network of extension offices in most centres and livestock production research farms.

Hartmann, A.M.; Summary: Namibian Country Study on Biosafety and Biotechnology

Developing a National Biosafety Framework
UNEP-GEF Workshop, Windhoek, 3-4 February 1999

18
The Directorate of Veterinary Services of MAWRD provides animal disease surveillance through its State veterinary offices in most major centres and a laboratory service centred at the Central Veterinary Laboratory in Windhoek and small regional laboratories in Grootfontein, Ondangwa and Gobabis. It further provides meat hygiene and public health services at the animal products processing plants.

Threats to the industry include the spread of CBPP, which is endemic in the northern communal areas and FMD from neighbouring countries, necessitating strict surveillance and vaccination in the northern communal areas. In the private sector, a number of private veterinarians provide animal health services.

A Farmer’s Co-operative provides a wide range of ancillary services, to the industry. A few private animal feed production firms are in operation.

Agricultural producers are represented by two national farmers unions, the Namibian Agricultural Union (NAU) and the Namibian National Farmer’s Union (NNFU).

An association of members of the industries supplying agricultural and veterinary remedies to the farming community has been founded in 1998 (AVPAN).

The Meat Board of Namibia, a statutory body, is the official marketing and controlling agency of livestock production. During 1997, approximately 226 000 head of cattle and 951 000 head of small stock were marketed. Only 6 372 locally produced pigs were marketed. (3)

Other livestock production sectors:

The dairy industry in Namibia is relatively small, with approximately 17.7 million litres of milk produced during 1997. Major producers are located in the Windhoek and Grootfontein areas. Processing takes place in Windhoek and Rietfontein. (3)

The Karakul pelt industry has shown a steady decline, with only 57 650 pelts marketed in 1997 compared with 510 414 in 1990. Wool production was negligible at 212 tonnes. (3)

The poultry industry produced 3.2 million dozen of eggs in 1997. (3)

The ostrich industry was subjected to some economic pressure due to trade restrictions as result of the presence of Newcastle Disease and the association of Crimean-Congo haemorrhagic fever with ostriches. (7)
Approximately 47,000 domesticated ostriches are farmed commercially. During 1997, 21,000 birds were slaughtered, 628 adult birds, 6,140 chicks and 23,102 eggs exported. (6)

Namibia's environment is characterised by four natural vegetation biomes; woodland, savanna, Namib and Karoo with 14 vegetation types and great species richness in various taxa.

Namibia's largely unspoiled, varied and unique environment has become an attraction to foreign tourists, which contributes greatly to the foreign currency earnings of the country.

The increased pressure on the environment due to the expanding human population and the growth in the tourism industry necessitates careful planning of the sustainable management of the natural resources. Some of these ecosystems are extremely fragile to disturbance by external factors and warrant extreme care with regard to development policies and procedures, including the use of biotechnology applications.

Namibia's environment is unique in many respects. The dry climate and lack of surface water caused a large number of species to evolve, that are adapted to such extreme conditions. There is a relatively high level of endemism of species with increasing endemism in the western more arid regions of the country, particularly the Kaoko escarpment, Sperrgebiet, Brukkaros and Brandberg regions. There are an estimated 683 endemic plant species, 1,541 endemic insect species, 164 endemic arachnid species, 6 frog species, 3 fish species, 59 reptile species, 14 mammal species, 14 bird species and an unknown number of endemic species of fungi in Namibia. (58)

Namibia has a large percentage of its land area (13.8%) under state protection, one of the highest of any country in Africa. This is to some degree augmented by privately owned reserves and conservancies. (17)

Despite that, it is inadequate for effective biodiversity conservation at a national scale, as some sites where the hotspots of species richness, endemism and conservation threats in various taxa coincide. A number of priority areas for additional conservation protection have been identified on the basis of qualitative indices for taxon richness, endemism, representation, conservation threat and unique habitats and landscapes. (17)

Under the Guidance of the National Biodiversity Programme of the Ministry of Environment and Tourism, a detailed Biodiversity Country Study has been undertaken recently. The Biodiversity Country Study Report was recently published.

Hartmann, A.M.; Summary: Namibian Country Study on Biosafety and Biotechnology

Developing a National Biosafety Framework
UNEP-GEF Workshop, Windhoek, 3-4 February 1999
Despite Namibia being such an arid country, wetlands comprise about 4% of Namibia’s surface area. Namibia’s wetlands are the country’s most productive and biologically diverse ecosystems. They include springs and ephemeral wetlands such as those of the Namib Desert, ephemeral rivers, the oshonas of northern central Namibia, and the floodplains of the perennial border rivers.

Although the Namib is one of the driest deserts in the world, a number of different kinds of wetland are found there. Relatively permanent pools, streams and lakelets fed by groundwater springs may, depending on the extent of evaporation, be relatively fresh or may be hypersaline. Ephemeral waters vary from rivers that run for short periods after rain has fallen upstream in the catchment to the pools they leave behind after flow has stopped, and pools formed as a result of rain falling in inward-draining basins. (24)

Namibia’s ephemeral rivers act as linear oases. (35) Although water is not found on the surface, the beds of most of these rivers hold significant quantities of water, and deep-rooted trees and other plants can tap directly into the water supply. The presence of this vegetation provides food and shelter for a variety of other organisms, so that longitudinal terrestrial ecosystems develop with complex communities of different taxa.

All of these wetlands are of intrinsic interest and value from the point of view of biodiversity because they support highly specialised species of invertebrates such as crustaceans and insects (and a few frogs). They also provide sources of drinking water for terrestrial vertebrates such as birds and mammals, which means that the distribution ranges of these animals expand during wetter periods.

Because of the isolated nature of many wetlands in Namibia, and of the island nature of Namibia as a centre of aridity, one might expect many groups of organisms to have endemic representatives. This is certainly true for some groups of organisms such as crustaceans, amphibians, reptiles, birds and plants. The taxonomy of many other groups is too poorly known at present for definitive statements to be made about levels of endemism.

Despite the fact that Namibia is an extremely arid country, and has no perennial rivers except at its borders, the Namibian freshwater fish fauna is fairly rich, with about 103 species having been recorded. Almost all of these are found in the northern and northeastern rivers, particularly associated with the rich floodplain wetlands of the Okavango and Zambezi catchments. Although only three species are endemic to the interior of Namibia, a number of others are confined to one or more of its bordering rivers. (23)
Unsustainably high water consumption resulted in dropping water tables. The development that has taken place, disregarding the limitations set by the scarcity of water in Namibia, the expense of securing water supply from ground water sources and the proximity of high human population density pose a threat to these wetlands. (S8)

Special care has to be taken to limit further threats caused by accidental or deliberate release of biotechnology products in these areas and their catchments, which may seriously affect their species composition and viability.

Desertification, which can be define as "land degradation in arid, semi-arid and sub-humid areas resulting various factors, including climatic variations and human activities", poses a major threat to the Namibian environment. (S5) Essentially, the processes are not the result of normal rainfall variation, but the human influence is almost always dominant, although drought may initiate the process. The processes of desertification are more or less irreversible.

Overgrazing, bush encroachment, overtilling and excessive wood harvesting for a variety of reasons, are major factors contributing to the process.

Biotechnology applications, that would perpetuate mono culture crop production or hamper the viability of the grass cover in a savanna ecosystem, could become a contributing factor to desertification.

Pollution of the environment can take place in various forms, ranging from littering, domestic waste, industrial waste to environmental contamination with toxic substances such as agro-chemicals. (S2)

As Namibia is not a highly industrialised country, it is unlikely that industrial waste buildup would become a major threat to the environment. It should however, be a priority to limit waste generation and regulate the safe disposal of hazardous waste.

Some biotechnology applications may aid in the bio-remediation of dump sites, while others may enhance the use of chemical and thus create a threat to the environment.

The mining industry is still one of the biggest single contributors to the GDP at 11.7% during 1997/1998. (S1)

The spectrum of mining activities includes:
- Diamond mining at Oranjemund, and offshore diamond mining in the Luderitz area
- Zinc at Rosh Pinah
- Manganese at Otjiseondu
- Fluorspar at Okoruso in the vicinity of Otjiwarongo

Hartmann, A.M.; Summary: Namibian Country Study on Biosafety and Biotechnology

Developing a National Biosafety Framework
UNEP/GEF Workshop, Windhoek, 3-4 February 1999
- Uranium at Rossing, near Swakopmund
- Gold at Navachab near Karibib
- Until early 1998 copper and lead at Tsumeb, Kombat and Otjihase

Although mining is an inherently destructive process, the mining impact is limited to less than 0.1% of Namibia’s surface area. Namibia’s mineral production includes gold, silver, diamonds, arsenic trioxide, copper, lead pyrite, tin, fluorspar and uranium.

Most types of mining operations require large volumes of water. The high demands of the Rossing Uranium mine, together with those of Swakopmund and Walvis Bay, is thought to have caused the degradation of the vegetation dependent upon the aquifer in the lower Kuiseb.

Namibia possesses a well developed asphalt road network, linking the larger commercial centers and providing a link to regional centers such as South Africa through Noordoewer and Ariamsvlei and Botswana and Zimbabwe via the Trans-Kalahari and Trans-Caprivi highways respectively. Most farming areas are accessible from the primary and secondary road network, although the road network is not yet optimally developed in the communal farming areas.

The rail network is limited to a north-south line from Tsumeb to South Africa via Windhoek, with links to Walvisbay and Luderitz at the coast.

Walvisbay is the major harbour with well developed infrastructure. Luderitz port is much smaller.

The aviation industry offers regular local, regional and international connections.

The connections to the region and further afield, through the road network, rail, ports and air pose a challenge to the biosafety framework, due to numerous ports of entry of potentially hazardous material and relatively man assisted dissemination locally.

The modern automated telecommunications network is rapidly expanding, with the aim of achieving access of 8 subscribers per 100 population by 2000. The cellular telephone system is expanding, with most larger centers being connected.
Chapter 3  Development Goals

Food security, health and economic growth to improve the standard of living of its population must be the fundamental aspirations of any developing nation.

In the context of including the use of modern biotechnology as an optional tool in the development of the country, some development aims are highlighted.

Namibia's development goals are spelled out in detail in the First National Development Plan (NDP1). The reader is referred to this document for detailed sectoral objectives, targets and strategies.

The NDP 1 recognizes that, in order to achieve the development goals, the dynamics of Namibia's population has to be harmonized with the country's resource potential.

The aim of improved household food security nationally and ultimately of food self-sufficiency is envisaged by encouraging increased volume and diversity of agricultural output. This should be achieved in a cost efficient and environmentally sustainable manner.

Rural poverty is to be reduced with more equitable distribution of the country's wealth. The rate of rural/urban migration has to be slowed down by improving the provision of essential services to the rural areas.

The objective to promote sustainable development within all sectors across all regions, equitable and sustainable utilization of renewable resources and the protection of biotic diversity are spelled out in NDP 1.

In the development and implementation of the industrial policy environmental issues are to receive increased recognition. The fact, that water is a limiting factor is addressed. Environmental assessment should be a pre-requisite for all industrial projects to ensure optimal use of Namibia's scarce natural resources and sustainable industrial growth.

The intensification of mineral exploration, development of new mines and local processing of industrial minerals are to be promoted. However, all mining operations are to be conducted within a framework of minimal environmental pollution and disturbance.

With regard to tertiary education, provision is made for ensuring relevance to national needs and closer cooperation between public and private sector. Multidisciplinary research and curriculum and programme review activities are to consider national development priorities.
Mobilization of resources by commercialization of services and industrial linkages are provided for in the objectives of the education development plan.

In the health sector eight specific objectives and targets were put forward. These include increasing the life expectancy, reducing the infant, child and maternal mortality rates; reducing the total fertility rates; improving health and quality of life through the promotion of environmental health at all levels; improving access to essential drugs and supplies; and reduce child undernutrition.

The Directorate: Research, Science and Technology, MHEVTST, produced a document on science and technology policy, which highlights the need for enabling mechanisms to enhance Namibia's capacity for science and modern technologies.

This policy document has as guiding principles that the programmes and initiatives be relevant, impacting and functional. It aims at strengthening national capacity to organise, motivate and carry out investigative research; and further appraise, develop, adapt and promote technologies that are appropriate for Namibia and to propagate the benefits and results of scientific investigations and their technological applications.

The Science and Technology policy makes provision for a Foundation for Research, Science and Technology and the establishment of a Science and Technology Trust.
Chapter 4  Biotechnology in perspective

Biotechnology is defined involving the integrated application of biological sciences such as genetics, molecular biology, microbiology and engineering to produce goods and/or services from living organisms or parts thereof. This definition of biotechnology is broad to encompass both new techniques such as genetic engineering and older techniques.

The evolution of biotechnology is characterised by major institutional changes and scientific developments. The technology has gone through three phases: starting with traditional household fermentation processes; leading to a large scale fermentation industry to the now established modern biotechnology characterised by high technology processes of genetic engineering, embryo modification and transfer, tissue culture, cloning of genetic material and others.

The emergence of the biotechnology industry was closely associated with rapid scientific breakthroughs in areas such as genetic engineering and tissue culture. Scientific research was the fundamental source of knowledge and opened opportunities for innovation. The institutional basis for scientific research was university laboratories. The U.S.A. universities invested considerable resources in basic scientific research in areas such as molecular biology, plant physiology and genetics. Most of their research was based on the exploitation of their knowledge of living matter. The involvement of universities in biotechnology and the fundamental role of scientific research have determined and guided the evolution of the technology in various ways. (39)

The growth of biotechnology as an industry has been characterised by a strong element of uncertainty. There has been, and there still is, uncertainty about the potential benefits of the emerging developments. This uncertainty continues to determine the levels and nature of investment devoted to research and development in biotechnology. Industry classifies it into low-, medium- and high risk research and development investment.

Biotechnology is a science or knowledge intensive technology. The growth of activities in biotechnology followed major scientific breakthroughs. Research and development activities leading to the establishment of the biotechnology industry were spurred by motivations and interests of scientists and scientific institutions and evolved on trajectories that initially had little to do with industrial demands.

Modern biotechnology has its origins in a scientific challenge to determine the secret code of life, which is by and large divorced from economic motivations, but has crucially contributed to determine the emergence of particular technological opportunities and the subsequent trajectories of technological innovation. (40)
Though the application of various biological techniques to produce goods from living organisms has been there for a long time, scientific breakthroughs in genetic engineering has revitalised some of the traditional techniques. Genetic engineering had to be integrated with other technologies, most notably process technologies related to large scale production.

The growth of biotechnology epitomises the nature of the process of technological change in general: the cumulativeness of technological change. Different biotechnological trajectories are evolving from classical techniques in chemistry, biological and engineering. The role of indigenous knowledge cannot be ignored in biotechnology. Our ability to use genetic engineering to produce disease resistant varieties of crops to no small measure depends on the existing knowledge, breeding techniques and production systems. (46)

Its impact is spread across various industries, ranging from pharmaceuticals to agriculture and ultimately affects the public by its socio-economic impact. It is also multidisciplinary in nature in the sense that it encompasses various techniques, which are used in an integrated way. Particular biotechnological techniques can be applied across a wide range of sectors and, therefore, different actors with different economic and social interests are involved. This not only raises the feature of complexity inherent in the process of technical change but also determines the nature and levels of investment in research and development. Furthermore, the technical feasibility of the potential applications of biotechnology, the time required to develop them and, above all, the economic returns which could be generated by innovations in the domain of biotechnology remain often uncertain during the early stages of investment. The potential impacts of some of the applications of biotechnology are also, to a large extent, uncertain. (52)

A related issue of uncertainty concerns the appropriation of the benefits or revenues arising from innovations of biotechnology. Most of the scientific information and knowledge as well as some of the raw materials underlying innovations of biotechnology are public domain. The information is accessible through scientific publications or can be acquired easily by firms or persons that have respective capabilities. The protection of biotechnology (products and processes), in this context, depends mainly on patents. Various problems arise which make protection of biotechnology under existing intellectual property regimes complex and controversial. (87)

First, biotechnology involves the use and transformation of genetic material which have often been obtained from developing countries often without compensation to local custodians of the material. Second, the technology is largely created on living matter and so ethical questions have been raised on whether such matter is patentable.
The two issues have been extensively discussed in various regional and international forums. They formed the most debatable part of the negotiations for the Convention on Biological Diversity. The first issue—relating to the sharing of the benefits of biotechnological innovations from genetic material acquired from developing countries—has partly been resolved. The resolution is deposited in Articles 15, 16 and 19 of the Convention. The second issue is still being discussed in the context of the debates on patenting life forms. The debates are conducted under the aegis of the Conference of Parties of the Convention and the World Trade Organisation (WTO).

Other outstanding issues include the question of trans-boundary movement and compensation and trade with non-parties. The country that supports the biggest biotechnology industry, the U.S.A., has not yet ratified the CBD. One can only view with suspicion, such a major player seeking arbitration at the WTO on the grounds of unfair trade restriction, if European countries find the risk of some applications unacceptable to allow importation!

**International trends in biotechnology research and development**

The international development of biotechnology has been associated with the growth of corporate involvement and investment in R&D. Corporate interest and involvement in biotechnology has grown in the United States of America (USA), Germany, France, Japan and a number of other industrialised European countries. The private sector interest in biotechnology has been stimulated by awareness of the potentials of new techniques such as genetic engineering and the prospects of getting new products on the market. The anticipated potentials of new biotechnological techniques have driven firms in the industrialised countries to invest in R&D and some have established in-house research facilities and expertise. In other cases, particularly in the agrochemical sector, some companies have acquired in-house expertise through take-over of smaller firms with considerable scientific expertise.

The development of innovative activities in the area of biotechnology has over the years been uneven across sectors and countries. Most of the biotechnology R&D has been in the pharmaceutical sector in particular and human health sector in general. In the USA a large share of R&D investment and activity has focused on human therapeutics, followed by diagnostics, chemicals, plant agriculture, animal agriculture and reagents. In Germany, pharmaceutical R&D and biochemical processing have received more priority. With increasing scientific research various technological opportunities are emerging. New areas of scientific research interest include the application of genetic engineering in environmental management as well as mining. But on the whole, a large share of global biotechnology R&D efforts is directed to medical biotechnology and the pharmaceutical sector in particular.
The possession of strong core scientific capabilities in areas underlying modern biotechnology has been a vital precondition of the engagement in the biotechnology enterprise and the attainment of high levels of technological performance. The USA companies, which for a long time have been leaders in the domain of biotechnology, have maintained their domination through the accumulation of scientific knowledge. They have mobilised scientific knowledge and expertise through various institutional arrangements. American universities and medical colleges have been the source of scientific knowledge and information to the companies. The companies have mobilised and utilised the scientific information and knowledge of these institutions through strategic alliances.\(^{45}\)

It should be noted that American scientific superiority has been the basis for an enormous technological gap but it has been used also by its competitors as a pool of knowledge on which to build new technological capabilities. Japanese companies have been at the forefront of searching and acquiring American scientific knowledge and information. They have done so through strategic institutional alliances.\(^{46}\)

The international developments in biotechnology have been associated with, and in many cases, have stimulated major changes in government policies. The USA has established policy regimes that are supportive of efforts of local biotechnology companies and has also given more financial support to basic research. The UK and Germany as well as other industrialised European countries have tended to provide more support to applied research.

The developments in biotechnology are reordering the world economy and changing patterns of international trade and relations. In the dynamic sectors such biochemical processing and pharmaceuticals, economic competitiveness and technological performance are gained and sustained through the strategic harnessing of scientific knowledge and application of new biotechnological techniques. It is the application of new techniques and the creation of technological capabilities that are the key to competitiveness of biotechnology companies in the USA, Japan and Germany.

As noted above, there are apparent differences across countries in the extent to which they command biotechnology. These differences are largely determined by the levels of technological capabilities countries possess. While access to new scientific and technological knowledge on biotechnology is relatively open, it is only those countries that make strategic investments in terms of accumulating the requisite capabilities to absorb and master new scientific information that exploit technological opportunities emerging from the global growth of biotechnology.

But the most striking feature of developing countries, particularly those of Africa, is the limited and unevenness of their technological capabilities in biotechnology.

Harmann, A.M.: Summary: Namibian Country Study on Biosafety and Biotechnology

Developing a National Biosafety Framework
UNEP/GEF Workshop. Windhoek, 3-4 February 1999
These countries have low absorptive capacities and their abilities to engage in technological learning to use new techniques of biotechnology are limited. For these countries to make significant steps in building up their capabilities and successfully engage in the application of biotechnology to enhance their economic growth and international competitiveness, they need to establish programmes aimed at creating core scientific and technological capabilities in various areas of biotechnology. This is a process involving investment in training and the establishment of specific biotechnology promotion institutions. It only after the African countries have accumulated capabilities for R&D, established institutions and formulated policies that promote local development of the technology that they will be able to move to high planes of technological performance and harness its potentials.

Developments in the field of biotechnology have accelerated tremendously in recent years and found applications in numerous fields. Such research and development requires very costly technological infrastructure. The race to patent new concepts and inventions has become so competitive and expensive, that only a few very large companies could survive. In recent years there was a tendency of these large companies taking over the smaller ones. Some of these large firms have an annual research and development budget far exceeding the national gross domestic product of most developing countries.

Although most companies claim that biotech offers the solutions to world food security for instance, it is important to put such statements into an objective perspective.

The Western European market for biotechnology applications is rapidly declining due to consumer resistance and regional legislation. In the face of the collapse of that market, firms are aggressively promoting their developments in the developing world in order to develop new markets to remain profitable.

The socio-economic impact in developing countries and the economic dependence of these countries on the industrialised countries being perpetuated, have to be pointed out.

Risks in the environment

Genetically engineered biochemicals have been released into the environment, and will continue to be released for the foreseeable future. The so-called "enhancement" chemicals, which are deliberately administered to animals. Bovine somatotropin (BST), also called bovine growth hormone, is one of the best known. It is a hormone synthesized with components of genetically engineered E. coli bacteria. Cows to which it is administered produce 15% more milk on the average than cows without BST treatment.

Hartmann, A.M.; Summary: Namibian Country Study on Biosafety and Biotechnology

Developing a National Biosafety Framework
UNE P-GEF Workshop, Windhoek, 3-4 February 1999
(This has familiar economic implications: production costs should fall for farmers using BST, eventually driving farmers who do not use it out of the market.) Its producer, Monsanto, points out that BST “is produced naturally” in cows, and it insists that the genetically engineered version is essentially the same proteinic hormone. However, concerns about the risks to human health of BST-milk focus on, inter alia, its content of fatty acids with longer chain-lengths than those of natural milk and the possible incorporation of stray amino acids in the engineered hormone, with consequences for the endocrine system. Among cows, the use of BST is linked to reduced fertility, decreased endocrine function, disturbances in bone growth, and increased incidence of mastitis, among other ill effects. Long-term effects on humans and other animals are yet unknown.

There are numerous other uncertainties involved in genetically engineering biochemicals, such as the effect on health of the widespread splicing of a gene from the Bacillus thuringiensis (Bt) bacterium into various crop plants, which causes them to secrete an insecticide toxin.

At least one genetically engineered biochemical, L-tryptophan, has been shown positively to have deleterious effects. L-tryptophan is an amino acid found naturally in meat, dairy products, and grains. The genetically engineered version, made by fermentation using certain bacteria cultured in glucose and anthranilic acid, is not perfectly identical to its natural prototype. The synthetic product is used as a nutritional supplement in foods. Between 1989 and 1992, over 1,500 cases of persons in the U.S. and other countries contracting eosinophilia, a blood disease, 38 of which resulted in death, were positively correlated to the ingestion of synthetic L-tryptophan. The product had been banned by the U.S. FDA in 1990.

An experiment in biotechnological nutritional enhancement has demonstrated the possible dangers to human health of genetic pleiotropy. Researchers at the University of Nebraska recently published their discovery that a high-protein albumin expressed in Brazil nuts causes an allergic reaction, like one associated with Brazil nuts, when the albumin is genetically reproduced in soy beans.

Risks to ecosystems

Probably more has been written about the risks biotechnology poses to ecosystems than on any other non-technical aspect of biotechnology. Risks to ecosystems are, of course, eventually risks to human health. Importantly, ecosystems also comprise agricultural land.

Genetically engineered organisms pose the greatest risks to ecosystems, since they can become dynamic living parts of them. The major application of agricultural biotechnology is the creation of crop plants which are tolerant to specific herbicides.
In the United States, herbicide-tolerant crops account for about 40% of all biotechnology field tests, and in the industrialized world they account for about 57%.

A great number of crop plants are being engineered for the capacity to persist in marginal environments and to propagate quickly. Both these traits confer to plants the potential to become noxious weeds, overrunning human and non-human ecosystems, displacing and killing plants and animals, upsetting the food chain, and permanently altering habitats.

Furthermore, there is the risk that these "weedy" characteristics could be passed on to wild relatives of crop plants by gene "introgression": the flow of genes from one plant species to another, mainly through cross-pollination. This could have devastating consequences.

Some crop plants have been engineered with viral-coat protein genes as mechanisms of resistance to viruses. The viral genes inserted into these plants could give rise to new viruses, through natural genetic recombination and other molecular biological processes already observed in genetically engineered plants. New viral pathogens could have an enormous impact on economically important crops, requiring considerable control costs.

The use of genetically engineered Bt crop plants, mentioned above, may increase the resistance of insect pests to the insecticide. If the Bt gene is spliced into a number of different plants, chance of widespread resistance is multiple. Some companies researching and developing a range of Bt crop plants, including maize and cotton. Widespread resistance would have a detrimental impact on organic and low-input farming, which rely on the Bt toxin in its naturally occurring bacterial form.

In addition, since genetically engineered crop plants, like conventional hybrids, are designed to yield a uniform product, their promotion will aggravate the already accelerating worldwide "genetic erosion," by which traditional cultivated varieties, with greater genetic diversity and potentially desirable traits, are displaced and eradicated.

Plants are not the only organisms that might threaten ecosystems. Genetically modified microorganisms (GMM's) are being developed for increased frost resistance in plants, enhanced nitrogen fixation, and bio-remediation. The genetically engineered bacterium Klebsiella planticola has been used for R&D in the last of these areas. When this GMM was tested in complex soil microcosms (self-contained units with field conditions, incubated in growth chambers), it killed wheat planted in the units. Microcosms containing the "parent" bacterium and experimental controls with no added bacteria had no noticeable effect on wheat.
The engineered \textit{K. planticola} was tested under several different environmental conditions, and the mechanism by which the wheat was killed or negatively affected differed from case to case. Furthermore, a variety of \textit{K. planticola} engineered to turn crop waste into ethanol was found to have an unexpected side-effect: The GMM cut in half the amounts of mycorrhizal fungi in the soil, crucial for nitrogen fixation. If such a GMM survived readily and spread widely, it could entail expensive control measures.

"Higher" animals are also being engineered for various purposes. They include insects, mice, and fish. The genetic engineering of fish, in particular, raises serious ecological issues. Although people around the world have practiced aquaculture on a small scale for centuries, fish remain relatively undomesticated. Unlike cows and other livestock, they can survive and breed in nature. They are also capable of traveling far and invading new ecosystems. Since fish inevitably escape from ponds and sea pens, genetically engineered varieties could multiply and out-compete endemic species. Genetic engineering of fish is moving ahead rapidly; some companies hope to begin selling fast-growing salmon to fish farmers in a few years.

Meanwhile, there is no comprehensive regulation in the U.S. governing genetically engineered animals—not even the requirement to notify the public of releases.

Trans-boundary movement of the products of biotechnology is also a profound concern. Not only will genetically engineered compounds and organisms be transported deliberately across international borders in the course of trade, but engineered, self-propagating organisms will spread wherever the ecological conditions are suitable. It should be needless to say that natural phenomena do not respect social categories. Therefore, it is worrisome that currently no comprehensive, legally binding international regulation of the unique products of modern biotechnology exists.

Attempts to establish such, as a protocol to the CBD, have been frustrated by the governments of industrialized countries and their supporters in the biotechnology industry. This ranks among the major political setbacks in countering the furious growth of the biotechnology industry.
Chapter 5  Regional status of biotechnology

Biotechnology research and development in sub-Saharan Africa vary from country to country, depending on funding, expertise and experience. The work is carried out mainly in international research institutions located or operating in the region, national research institutions and universities.

There is also evidence that the private sector, including para-statal organisations, is starting to become interested in the prospects of biotechnology and are starting to fund local research institutions to conduct certain types of biotechnology research. These are mainly large corporations with financial resources but limited research capability, especially in the high technology field.

There are no institutes, specifically dedicated to biotechnology. Feasibility studies have been carried out in countries such as Kenya and Burundi to explore the possibility of setting up biotechnology centres. (48)

Most of the current biotechnology research and development activities are focused on improving productivity in the agricultural sector. The direction of biotechnology research in Africa is influenced by the traditional research agenda. The research is conducted in public universities and in some of the national agricultural research centres. A number of international research organisations located in the region are also engaged in biotechnology research and development.

African countries are at different levels of development in biotechnology. There are generally three categories in terms of their stage in developing and exploiting biotechnology:

The first group is what is generally referred to as low level biotechnology countries. These are countries that have confined their biotechnological activities to traditional techniques such as fermentation. They are yet to acquire second generation biotechnologies (e.g. tissue culture technologies) or even to higher levels in the development of the technology. Such countries include Somalia, Eritrea and Burundi and several others.

The second category of countries is middle level biotechnology countries. These countries are engaged in second generation biotechnology (e.g. tissue culture and in vitro techniques). They include Tanzania, Zambia, Nigeria, Ghana, Kenya and Ethiopia.

The last category is the higher level biotechnology countries. These countries (which include Zimbabwe, South Africa and Egypt) are already engaged in third generation biotechnology Research and Development. They are exploiting genetic engineering techniques. (48)
Although many of the countries in the region have had a long tradition in research, especially in agriculture, their manpower base is still weak compared to the tasks that need to be performed. Since biotechnology is science-intensive, the quality of training and level of technical competence needs to be high. Using the national agricultural research institutes as indicators of the available capability, the region's institutions are staffed by inadequately trained people. Less than 8% of the local scientists in most Sub-Saharan African countries have doctoral training and some 57% have not undergone postgraduate training at all.

The share of research activities in the local research institutions is relatively small and most of the resources are used for general administration. It is estimated that only 15% of finances in the institutions is spend on research in Kenya. The same situation applies to the utilisation of manpower in the research institutions. For example, the national research institutions in Kenya devote only 9.6% of their manpower to research, the rest is devoted to support activities. (469)
Chapter 6  Local capacity to deal with biotechnology

For a developing country to employ modern biotechnologies with potentially far reaching effects, it is essential to meet certain requirements to do so safely. These requirements can briefly be described as being:

- familiarity with the processes and procedures involved
- institutional infrastructure and human resource capacity
- appropriate regulation
- suitability of the technology to the development aims
- economic and environmental sustainability
- local and regional opportunities
- local and international cooperation and communication

To develop a whole new institutional infrastructure to deal with biotechnology and biosafety would not be economically feasible.

Existing local structures and resources were assessed, in order to determine to what extent Namibia meets these requirements.

There are a number of institutions in Namibia actively utilising biotechnology applications and conducting research on biotechnology.

These include:

- National Forensic Science Institute
  Field: Forensic science
  The institute is one of two internationally accredited forensic science institutes on the continent. (The other being The South African National Forensic Institute) This accreditation requires strict adherence to the ISO 9000 standards. It can thus be assumed that the pre-requisites to safely conduct biotechnology research and use various biotechnology applications are met.
  Uses biotechnology applications for:
  • Serology
  • Species typing
  • Forensic DNA
  • Toxicology
  • Biochemistry
  Biotechnology applications used:
  • Plasmaphoresis
  • DNA Polymerase chain reaction
  • Homogenous immunoenzyme technology
  • Optical comparison spectroscopy

Hartmann, A.M.: Summary: Namibian Country Study on Biosafety and Biotechnology

Developing a National Biosafety Framework
UNEP-GEF Workshop, Windhoek, 3-4 February, 1999
Current research involving biotechnology:
- Forensic sciences
- Testing methodology
- Calibration methodology

Central Veterinary Laboratory
Field: Animal production and veterinary diagnostics
Uses biotechnology applications for:
- Immuno pathology
- Virus isolation
- Bacteriology
Biotechnology applications used:
- PCR
- Cloning and sequencing
Current research involving biotechnology:
- Typing of *Mycoplasma mycoides subsp. mycoides*, the causative organism of contagious bovine pleuropneumonia for potential vaccine development;

Medical Laboratory Services
Field: Medical diagnostics
Uses biotechnology applications for:
- Serology
- Biochemistry
- Virology
Biotechnology applications used:
- Commercially available test kits based on monoclonal antibodies

Palmdat Namibia
Field: Crop production
Purpose of research:
- *In vitro* propagation of date palms
Biotechnology applications successfully employed:
- Embryogenesis
- Organogenesis

MAWRD Division Plant Production Research
Current work limited to *in vitro* multiplication of root crops (casava);
- Including field testing
In order to effectively exercise regulatory control over biotechnology in Namibia, the following, amongst others, has to be considered:

- What is likely to be introduced or developed?
- Is it potentially hazardous?
- Who is likely to be involved?
- What are the likely routes taken and ports of entry going to be, in the case of imports?
- Who will be on site at these ports of entry to exercise control?
- How is the relevant official equipped to deal with the situation?
- How can the official recognize the material?

For legal entry into the country, official ports of entry have to be utilized; these include:

- border posts along the major roads linking the country to South Africa, Botswana, Angola and Zambia;
- Luderitz and Walvis Bay harbours;
- Keetmanshoop, Hosea Kutako International, Grootfontein, Walvis Bay, Rundu and Mapacha airports;
- Windhoek post office;

These entry points are manned by Customs officials, rarely phyto-sanitary, veterinary control and environmental management officials. Even if importation is subject to import permits and detailed labeling is required, the local officials in conjunction with the permit issuing authority, have to be well familiarised with the relevant issues to deal with the situation.

Agencies that can exercise control include:

- Ministry of Agriculture, Water and Rural Development
  - Directorate of Veterinary Services
    Implementing agency for animal disease control, public health for food of animal origin; Current legislation, which does not include biotechnology, and limited familiarity with biotechnology limits regulatory capacity; Import control by issue of import permits, where conditions can be set and certification of origin be demanded presents scope for control; Legislation makes provision for live animals, animal products and fomites which may present risk to animal health status; Well developed network of animal health inspection officials;
  - Directorate Law Enforcement
    - Phyto-sanitary Control
      Implementing agency of phyto-sanitary legislation; Draft Plant Quarantine Act to replace outdated Agricultural Pests Act, 3 of 1973 and Draft Seed Bill, which makes provision for IPR;

Hartmann, A.M.; Summary: Namibian Country Study on Biosafety and Biotechnology

Developing a National Biosafety Framework
UNEP-GEF Workshop, Windhoek, 3-4 February 1999
Scope for control:
Importation of plants only with import permit issued by the institution;
Conditions regarding origin and certification regarding disease status can be set to include biotechnology;

- Registrar: Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 36 of 1947
  Scope for control:
  Required registration of products marketed as fertilizer, farm feed, agricultural remedy or stock remedy makes provision of certification of content and labeling which is valid for 1 year;
  Accepts S.A. registration of products;
  Currently probably the most suited to exercise control over importation and local experimentation and commercialisation of products;

- Registrar: Livestock Improvement Act
  Importation of live animals under permit with conditions that can be set to protect genetic resources;

- Ministry of Environment and Tourism
  - Directorate of Environmental Affairs
    Not directly involved in regulation;
    Offers resource base to be utilised to determine environmental impacts and policy guidance;

  - Resource Management: Specialist Support Services
    Sets conditions for imports, research and utilisation in fields relevant to environment protection, based on impact assessment and review by experts;

- Ministry of Health and Social Services
  - Directorate Pharmaceutical Services
    Regulatory capacity limited to registration and use of medicines and related substances;

- Ministry of Finance
  Customs and Excise officials are the first line of control in the case of imports. Limited familiarity with biotechnology limits regulatory capacity. Need to be assisted by other relevant institutions.
- **Ministry of Trade and Industry**
  Becomes relevant to foreign investment and importation of commodities; Issues import permits based on recommendation of relevant official bodies, which can include conditions on issues pertaining to biotechnology *per se*.

- **Ministry of Labour and Human Resource Development**
  Implementing agency for occupational health legislation, which includes control over potentially hazardous substances, although the MHSS is involved in the practical enforcement of legislation.

- **Namibian Agronomic Board**
  As official agronomic marketing agency in close contact with similar institutions within the region; By approving/rejecting applications for import of controlled agronomic products on basis of quality analysis, may have appropriate capacity to regulate imports; Constraint: Regulatory capacity limited to controlled agricultural products;

- **Professional Councils / Statutory bodies**
  Statutory Bodies regulating professional ethics, discipline and maintenance of minimum standards; Although current legislation, excluding biotechnology, and limited familiarity with biotechnology *per se* limits regulatory capacity, these councils can enforce guidelines with regard to a code of conduct decided upon the regulatory framework;
  - Veterinary Council
  - Medical and Dental Council
  - Pharmacy Board
  - Laboratory Board

- **Professional Associations**
  In most cases, these associations are primarily geared to represent professional interests of members of the profession, although the original purpose was to enhance the image of the profession and maintain a code of ethics and high professional standards. There is potential for an indirect regulatory function based on voluntary code of conduct on matters pertaining to biotechnology and biosafety for its members, although limited familiarity with biotechnology is a limiting factor;

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Hartmann, A.M.; *Summary: Namibian Country Study on Biosafety and Biotechnology*

*Developing a National Biosafety Framework*

*UNEP/GEF Workshop, Windhoek, 3-4 February 1999*
Examples include:

- Veterinary Association of Namibia (VAN)
- Agricultural and Veterinary Products Association of Namibia (AVPAN)
- Laboratory Technicians Association
  There is an effort under way to establish an association encompassing all sectors of laboratory work
- Agricultural Scientific Society of Namibia (AGRISSON)
- Namibian Agricultural Union (NAU)
- Namibian National Farmers Union (NNFU)
- Medical Association of Namibia

The overall capacity to effectively manage biotechnology and biosafety seems to lie in the hands of a few key individuals in a few key institutions.

Local capacity to offer education in biotechnology is very limited. There are indications of inclusion into the curricula at the Science Faculty of UNAM.
Chapter 7 Conclusions

The conclusions drawn and presented in this report are the personal opinion of the author, and are based on broadly based research including consultation with experts in various relevant fields, both locally and internationally.

A concerted attempt was made to establish a very broad base of input into this study by interested and affected parties. A very disappointing poor response was received.
This can be interpreted as
- ignorance and lack of interest
- protectionism of personal interests
both of which are serious causes for concern.

The views of those, who failed to respond to the invitation to participate, for whatever reason, cannot be considered in the analysis and are thus not represented in the conclusions in this report.

There are, however, in the scientific community a number of individuals and institutions where there is an obvious commitment to science and development based on information sharing and credible evaluation of the facts.

As a holistic approach to biotechnology and its place in development is aimed at, the conclusions drawn were not limited to strictly the issue of biotechnology, but rather encompass the total environment in which the controlled utilisation of the technology is to take place.

Based on critical evaluation of facts arising from the research, the following conclusions arise:

General Observations

- Public Awareness
The level of public awareness on biotechnology issues encountered during this study was extremely low, even amongst the so-called intellectual society.
For an issue that is widely, and often hotly, debated world wide, and with local access to world wide publications, the internet and other information sources; possible explanations for this may be:
- poor level of education
- an apathetic society
- unwillingness or inability of local media to report on general knowledge topics and thus fulfil their function of a medium for public education

Hartmann, A.M.: Summary: Namibian Country Study on Biosafety and Biotechnology

Developing a National Biosafety Framework
UNEP-GEP Workshop, Windhoek, 3-4 February 1999
- **Society Work Ethics and Productivity**
  There seems to be a tendency toward limited goal setting with regard to employment in the Namibian Society. The sense of achievement tends to be limited to securing a job and not to contribute to the development of society by optimal input. This leads to poor productivity of the workforce, particularly in the civil service.

- **Education**
  Basic and secondary education is deficient in developing an aptitude for science. Students have weak basis for graduate study in science. Attitude to lifelong learning and applying knowledge to science, together with limited goal setting, is cause for concern. If future potential technicians or scientists consider research as just another job, it adds risk to work with GMO's.

- **Economic dependence**
  The general attitude seems to be to find donor money for sometimes extravagant goals with regard to facilities etc. That has been the downfall of many developments for scientific innovation.

**Findings specifically relevant to biotechnology**

- **Realistic needs for biotechnology**
  - **Agricultural crop production**
    Given the environmental, economic and operator related constraints, it is most unlikely that even the large scale use of biotechnology derived crops will ensure household food security. Traditional methods of crop cultivation should rather be improved to be more effective, diversification of agriculture to ensure income generation Incentives by creating markets for surplus crops will do more for food security
    High output genetically modified crops require more management, water fertilizer
    [key players: MAWRD, Co-op, NAU]

  - **Livestock production**
    Stock disease control through local vaccine production CBPP
    Genetic typing for stud animals
    Biotechnology unlikely to make a positive impact in productivity
    Range land management practices to be improved
    Maintain status of exporter of wholesome beef
    [key players: MAWRD,DVS, CVL, veterinarians NAU, feed industry]
- **Health**
  Malaria remains a major factor, particularly in the Northern areas. It may lend itself to investigation with regard typing for diagnostics. Diagnostics and hormonal medicines eg. Insulin are widely used and pose no risk.
  New developments regarding vaccines, including HIV

- **Bio-remediation**
  Very limited scope in the absence of major pollution. Water purification systems may benefit from appropriate applications, particularly screening for contaminants like Hepatitis etc.
  Some methods to reduce sulfides/sulfites may have localised applications.

- **Institutional Capacity**

  - **Public sector Regulatory functions**

    The basic infrastructure exists, there are however some personnel constraints.
    Key players:
    MAWRD
    - Central Veterinary Laboratory
    - Extension and Engineering: Subdivision Law Enforcement
    - Registrar: Act 36 of 1947
    MET
    - DEA
    - Resource Management: Specialist Support Services

  - **Human Resource Capacity**

    Basic knowledge exists, however urgent specific training of decision makers
    Will have to get Customs & Excise personnel informed

- **Risks of Biotechnology in the Namibian Context**

  - **Environmental**
    - Areas of unique biodiversity, the wetlands of the floodplains along the northern perennial rivers and oshonas, are overlapping with the highest population density. Although biotech crops are unlikely to make a major impact on food security, the areas may be politically targeted for high profile technology.

  - **Health**
    - If any risk thus far, then only food related
- **Economic**
  - If the large scale use is promoted, will become economically dependent on supplier countries;
  - Alliances between major companies and academic institutions to be viewed with care

- **Laboratory use, Research and Development**
  Only CVL, Forensic Science Institute and Palmdat beyond the level of commercial test kits.

- **Local, sub-regional, regional and global networking**
  - **Local co-operation and networking**
    - Poor communication exists between various institutions.
    - Proper communication essential to initiate need orientated research.
    - Poor communication, which is believed to be based on individual empire building tendencies, will be a major limiting factor to sensible sharing of resources, laboratory facilities.
    - Proposed Science and Technology Policy may help to overcome this problem

- **Regional co-operation and networking**
  - Regional focal point at Harare was not optimally functional
  - Drive by South Africa to run a regional focal point

- **Global co-operation and networking**
  - Avenues exist to establish wide networking
  - Participation at Biosafety Working group meetings and trade negotiations limited by representation by only one country representative, as there are usually 4 concurrent sessions

- **Education**
  - **Opportunities**
    - **Local**
      Very limited, UNAM not yet equipped to offer post-graduate training
    - **Sub-regional**
      Zimbabwe offers training up to Masters degree
- Various South Africa Universities offer training, graduate up to PhD.
- Numerous short duration courses offered at various institutes
- Refer FRD Directory of Biotechnology in South Africa
Chapter 8  Recommendations

8.1  General Recommendations

- Urgent interim control measures be instituted on importation of GMO products;
- Applications under these measures to be reviewed by NABA in association with international experts and existing regional authorities;
- Establish the official controlling body
- Develop national policy and legislation
- Establish a broader base of participation in NABA
- Establish opportunities and mechanisms for training
- Raise public awareness

8.2  Official controlling body

8.2.1  Structure

A multi-disciplinary advisory council, called The Namibian Biosafety Advisory Council (NBAC) for the purpose of this discussion, should be established, which advises relevant responsible government ministries on issues pertaining to biotechnology and biosafety.

The NBAC should function on the same principles and have the same status as professional statutory bodies, such as The Veterinary Council, and be accountable to one Ministry, which chairs the council and which is suggested to be MHEVTST.

Broad representation of experts in the field of biotechnology from relevant ministries, academic institutions and the private sector, viz.:

- MET
  - Directorate Environmental Affairs
  - Resource Management: Specialist Support Services
- MAWRD
  - Directorate Extension and Engineering, Subdivision Law Enforcement
  - Directorate Veterinary Services
  - Directorate Agricultural Research and Training
- MHSS
- National Forensic Science Institute
- University of Namibia
- Co-opted experts from other fields and institutions
- Representatives of the biotechnology industry

Hartmann, A.M.: Summary: Namibian Country Study on Biosafety and Biotechnology

Developing a National Biosafety Framework
UNEP-GEF Workshop, Windhoek, 3-4 February 1999
8.2.2 Functions and procedures

Provision should be made within the NBAC for the regulation of importation of and work with GMO's by:
- Registration of facilities
- Registration of projects, products and processes
- Registration of personnel

Provision should be made for the NBAC to determine:
- the minimum standard for facilities,
- protocols for risk assessment and management
- the competence of the personnel involved
- formal in which applications are to be submitted

and depending on its review approve, refer or reject applications.

8.3 Biotechnology Legislation

There are two ways in which to establish the urgently needed legal framework for biotechnology in Namibia;

- amending existing relevant sector legislation
  or
- drafting a new bill;

As there is no relevant cross sectoral legislation in place in Namibia, it is probably not an option to amend sectoral legislation, as reference would have to be made to a range of relevant, even if in some cases remotely so, sectoral legislation. The legislation that would have to be amended, includes:

Agriculture
- Soil conservation Act 76 of 1969
- Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act 36 of 1947
- Prevention of Undesirable Residue in Meat Act 21 of 1991
- Animal Diseases and Pests Act 13 of 1956
- Agricultural Pests Act 3 of 1973
- Livestock improvement Act 25 of 1977
- Meat Industry Act 12 of 1981
- Agronomic Industry Act 20 of 1992
- Pelts and Wool Act 14 of 1982
- Plant Breeders' Rights Act 15 of 1976
- Draft Seed Bill
- Draft Plant Quarantine Act

Hartmann, A.M.: Summary: Namibian Country Study on Biosafety and Biotechnology

Developing a National Biosafety Framework
UNEP-GEF Workshop, Windhoek, 3-4 February 1999
Environment
- Draft Environment Management Act
- Nature Conservation Ordinance 4 of 1975
- Forest Act 72 of 1968
- Sea Fisheries Act 29 of 1992
- Preservation of Trees and Forest Ordinance 32 of 1952
- Water Act 54 of 1956
- Draft Wildlife and Parks Management Bill

Health
- Public Health Act
- Hospital and Health Facilities Act
- Human Tissues Act
- Medicines and Related Substances Control Act 101 of 1965
- Labour Act 6 of 1992 (Regulation 176-195)
- Draft Pharmaceutical Bill

It would be in the interest of Namibia to draft specific biotechnology and biosafety legislation as a matter of urgency.

For guidance
The Norwegian Gene Technology Act (Act 38 of 2 April 1993)
and the recent South African biotechnology legislation,
were reviewed.

The South African Genetically Modified Organisms Act of 1997 is considered an appropriate framework upon which the Namibian Legislation should be based.

8.4 National Policy on Biosafety

National policy on biosafety should make provision for the employment of precautionary principles.

With regard to research and development, the policy should prevent Namibia becoming a testing ground for research undertaken elsewhere.

Local research should be local need orientated and not of purely academic interest.
8.5 Technical Guidelines for work with genetically modified organisms

Technical guidelines on work with GMO's have been drafted. This comprehensive document has been adapted from the British and South African technical guidelines and makes reference to the following:

APPLICATION OF OTHER HEALTH AND SAFETY LEGISLATION TO WORK INVOLVING GENETIC MODIFICATION

PART 1A
Genetic modification and COSHH
Biological agents
Prevention of exposure to a biological agent
The GMM Group I/II classification scheme and biological agents Hazard Groups 1 to 4

PART 1B
Oncogenes and COSHH

PART 1C
Management of Health and Safety at Work Regulations 1992
Management responsibilities
Biological Safety Officers
Training and supervision

PART 1D
Genetic modification safety committees
Constitution
Safety Representatives and Safety Committee Regulations

PART 1E
Health surveillance
Low risk work with GMO's
Higher risk work with GMO's
Health surveillance procedures
Records of exposure
Work with oncogenes and other hazardous sequences

PART 2
RISK ASSESSMENT OF GENETICALLY MODIFIED ORGANISMS

Introduction
Risk assessments under the Contained Use Regulations
Risk assessment parameters
Risk assessment for environmental protection
"Harm" to the environment and "Risk"
Risk assessments under the Genetically Modified Organisms (Risk Assessment) (Records and Exemptions) Regulations 1996, as amended in 1997 and Part VI of the EPA 1990
Summary of the risk assessment

Hartmann, A.M.; Summary: Namibian Country Study on Biosafety and Biotechnology

Developing a National Biosafety Framework
UNEP GEF Workshop, Windhoek, 3-4 February 1999
PART 2A
RISK ASSESSMENT OF GENETICALLY MODIFIED MICRO-ORGANISMS OTHER THAN EUKARYOTIC VIRUSES

Introduction
Structure of the guidance
(i) Consideration of the predicted properties of the GMM to determine if there are any potential mechanisms by which it could represent a hazard to human health.
(ii) Consideration of the likelihood that the GMM could actually cause harm to human health.
(iii) The assignment of the general controls necessary to safeguard human health i.e. the allocation of a containment level.
(iv) Consideration of the nature of the work to be undertaken.
(v) The identification of any hazards to the environment and the assignment of any additional containment measures.
(vi) Classification into Group I or II.

Annex I Hazard identification based on access, expression and damage (the 'Brenner Scheme').
Annex II Examples of host-vector systems and access factors.
Annex III Additional guidance on specific types of GM work.
Annex IV Environmental hazards other than potential to survive, establish and disseminate.

PART 2B
RISK ASSESSMENT OF GENETICALLY MODIFIED HUMAN AND ANIMAL VIRUSES AND VIRAL VECTORS

Introduction
Gene therapy
Structure of the guidance
(i) Consideration of the predicted properties of the genetically modified virus to determine if there are any potential mechanisms by which it could represent a hazard to human health.
(a) Hazards associated with the vector.
(b) Hazards arising directly from the inserted gene product.
(c) Hazards arising from the alteration of existing pathogenic traits.
(ii) Consideration of the likelihood that the genetically modified virus could actually cause harm to human health.
(iii) Assignment of general control measures to safeguard human health.
(iv) Consideration of the nature of the work to be undertaken.
(v) Risk assessment for environmental protection.
(vi) Classification into Group I or II.
Annex I  Extract from the Guidance List of Biological Agents
Annex II  Pathogens controlled by the Agriculture and Fisheries
          Departments. Pathogens of animals and poultry
Annex III Guidance on commonly used viral vectors
          Adenoviruses
          Retroviruses
          Alphaviruses
          Baculoviruses
          Herpes simplex
          Poxviruses

PART 3
REGULATORY REQUIREMENTS FOR DETERMINING GMO CONTAINMENT AND
CONTROL MEASURES AND GENERAL GUIDANCE

Introduction
Relevant regulations and other guidance
The Contained Use Regulations
The Control of Substances Hazardous to Health (COSHH) Regulations 1994
Management of Health and Safety at Work Regulations (MHSWR)1992
The Health and Safety at Work etc. Act 1974 (HSW Act)
Discussion of the general requirements of the Contained Use Regulations and possible
means of compliance
Local rules
Containment and control
Selecting containment
Environmental considerations
Animal containment
Measures for securing adequate control

PART 3 A
SELECTION OF CONTAINMENT AND CONTROL

Introduction
Scope
Selection of containment and control measures
Small vs. large scale
Explanation of terms
Section I: Containment and control measures for small scale laboratory activities
ACGM containment level 1
ACGM containment level 2
ACGM containment level 3
ACGM containment level 4
Section II: Containment and control measures for large scale laboratory activities
ACGM containment level B1
ACGM containment level B2
ACGM containment level B3
ACGM containment level B4
Table 1  Containment and control measures for small scale activities
Table 2  Containment and control measures for large scale activities
Annex I   Containment and control measures for work with
          naked oncogenic DNA
Annex II  Microbiological safety cabinets
Annex III Chemical inactivation of GMM's
Annex IV  Fumigation

PART 4
GUIDELINES FOR TRIAL RELEASES OF GENETICALLY MODIFIED PLANTS IN
NAMIBIA
Introduction
Risk assessment
Monitoring
Programmes of work
Annex A  Releases in practice
Part I:  Guidelines
Part II:  Examples
Annex B  Monitoring Methods
Annex C  Questionnaire on trial releases
Annex D  Questionnaire for general releases
As an example, the section "Releases in Practice" is spelled out below:

**Part One: General Guidelines for a Typical Release**

1. This general outline of a typical release is particularly relevant to releases in the managed environments characteristic of agriculture and horticulture.

2. The monitoring methods will vary from release to release depending primarily upon the assessed risks and the management of an individual release.

3. Part 1 of this Annex sets out general guidelines for a typical release. By contrast, Part 2 presents hypothetical worked examples of releases with differing hazard potential, and therefore differing requirements indicated by the risk assessment.

**Risk assessment and the pre-release survey**

4. The first step of assessment is to identify any hazards associated with the proposed release, for example:

   i. an insect resistant plant harming non-target organisms such as bees or leading to a population of insects with resistance to an insecticide; or

   ii. the formation of a herbicide-tolerant weed population by introgression and subsequent dispersal of the inserted (herbicide tolerance) character(s) in wild or feral relatives.

5. Once any hazards and any methods of realisation are identified, a qualitative assessment must be made of the magnitude of possible harm, and the likelihood that these hazards may result in damage to the environment. The likelihood may be high, medium, low or negligible and the risk of damage high, medium, low or effectively zero.

6. Any identified hazards that may arise from the release should be addressed. These are predominantly related to the risk that the genetically modified plant can cause harm, for example that availability of potential recipients might cause damage by allowing introgression and subsequent dispersal of the inserted character(s) - such as promoting the spread of a population of insect resistant plants.

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Hartmann, A.M.; **Summary: Namibian Country Study on Biosafety and Biotechnology**

*Developing a National Biosafety Framework*

UNEP:GEF Workshop, Windhoek, 3-4 February 1999
7. A key element of the risk assessment is to examine the environment where the release is to occur to identify which (if any) of the hazards are likely to be realised. The pre-release survey is an essential part of this examination.

8. The extent and depth of the survey should aim to provide enough data to satisfy all the concerns that are addressed in the risk assessment. Where this is not the case, risk management safeguards will be required, whether the risk is high, medium or uncertain (see paragraph 12).

9. If dispersal is a cause for concern, then isolation of the release plot from compatible crops or species should be considered. Isolation could be physical, i.e. by distance, or biological, for example by avoiding (or preventing) the genetically modified plant flowering simultaneously with compatible species.

10. Other factors which may need to be considered include

i. **Species**: The plant released; volunteers and feral populations; related crops; compatible wild relatives. Visits by pollinators or other fauna may also be relevant.

ii. **Area**: The release plot and the designated dispersal area around it. If relevant, include all plants that can be expected to be recipients of pollen.

11. The estimated dispersal area might include nearby fields or plots of the plant to be released. If appropriate, it may also include nearby gardens. For example:

i. for wind-pollinated plants, the potential dispersal area for pollen may depend on the size of the release plot, i.e. the number of plants contributing to the pool of pollen;

ii. for insect-pollinated plants, the availability of pollinators (e.g. honey bees) may be relevant.

12. Surrounding a release by non-transgenic (trap) plants could help ensure that any pollen from the transgenic plants is trapped and does not travel great distances.

13. If there is a high population of receptive plants in the area surrounding the trial site (including crops grown for seed and wild relatives), this is likely to affect the dispersal area.

Hartmann, A.M.; Summary: Namibian Country Study on Biosafety and Biotechnology

*Developing a National Biosafety Framework*  
*UNEP GEF Workshop, Windhaek, 3–4 February 1999*
14. It remains possible that the pre-release survey does not provide sufficient data to address any uncertainty identified by the risk assessment. In such cases, management may be required to ensure that harm does not arise. Monitoring would be required to ensure that any management procedures are effective.

15. For example, there may be a degree of uncertainty about the persistence and spread of the genetically modified plant in the environment.
   
i. If spread (but not persistence) was judged likely to result in harm to human health or the environment, management safeguards would be needed to prevent spread occurring. Monitoring would thus need to concentrate on showing that such spread had not occurred.

   ii. In addition, voluntary monitoring undertaken during the release stage might address any uncertainty regarding the survival of the genetically modified plant. Such monitoring could concentrate on collecting data on survival of the genetically modified plant on the release plot.

**Monitoring during release**

16. Monitoring during release aims to assess the efficacy of any risk management safeguards applied to the release. This should detect whether there is any risk of harm, caused for example by introgression with potential recipients.

17. For example, if the presence of available pollen recipients within the dispersal area is assessed to be a risk, their number should be kept below the level at which harm might occur.

18. The frequency of monitoring should take account of the growth rate and stage of maturity of relevant plants.

19. Monitoring data obtained during and after the release from such voluntary experiments to test survival could help address the uncertainty. A more precise risk assessment could then be made for a subsequent release proposal, and consequently, could allow risk management safeguards to be reduced.
Post-release monitoring

20. Where the risk assessment identifies that continued presence of the released genetically modified plant or gene presents a risk of harm, post-release monitoring will need to concentrate on confirming the removal of the released plants.

21. Where appropriate, monitoring should concentrate on detecting and controlling any volunteer plants arising from the release.

22. In some cases there may be uncertainty regarding the risk of harm from continued presence of an organism, especially over the long term. Post-release monitoring should then be designed to provide data to enable the uncertainty to be resolved.

23. Factors to be taken into account include:
   i. seasonal effects, such as flowering and likely germination times, and
   ii. post-trial treatment of the release site.
   iii. Longevity of seed or tubers in soil may be particularly relevant for some releases. Post-release monitoring of a trial site may give basic data on, for example, the longevity of propagules.

24. In general, where flowering creates a risk of harm, e.g. by gene spread, monitoring visits should be planned to coincide with potential flowering times of volunteer plants. If volunteer plants do occur and subsequently flower, the dispersal area should be monitored for potential pollen recipients, or their offspring. Any such plants found should be destroyed.

25. Monitoring information could indicate how long transgenic plants could continue to appear, (and hence indicate the likely duration of post-release monitoring: see number 27).

26. Estimates of survival times for volunteers should take into account the effects of the volunteer control practices applied to the site.

27. In all cases, the extent and duration of the monitoring should be sufficient to prevent or minimise damage to the environment over the longer term as a consequence of the release.
Part Two: Examples of releases

28. This annex gives examples of two hypothetical releases:
   i. potato with modifications to carbohydrate metabolism,
      and
   ii. oil-seed rape with inserted genes for a pharmaceutical protein.

   They must not be regarded as definitive; real releases which appear to be
   similar may require different risk management elements, depending on the
   risk assessment. This may be affected by the local environment of the
   release.
   Procedures for other types of release may vary markedly.

29. Identification of Hazards:

Release a) Potato

Potatoes altered in carbohydrate metabolism. Not considered to be a hazard to
human health; low hazard to the environment, genetic modification does not
affect tuber survival or weediness. The magnitude of potential harm to the
environment is negligible. Risk of harm, effectively zero.

   Management safeguards required:

   Prevention of entry of genetically modified potatoes into the food chain.

30. Identification of Hazards:

Release b) pharmaceutical oil-seed rape.
Genes known NOT to be expressed in pollen, but are expressed in seeds and
leaves. Protein known to be immunogenic.

Identified hazards:

(i) considered to be a hazard to human or animal health if exposure to
large amounts of the protein occurs; (ii) possible spread of the gene to
weedy relatives. The magnitude and significance of potential harm to the
environment is moderate. The likelihood of harmful effects being realised
depends on (i) exposure to genetically modified plant material, and (ii)
availability of pollen recipients in dispersal area and numbers of transgenic
plants remaining in the release area. Overall risk of harm, medium.
Management safeguards required:

i. Prevention of exposure to growing plants - site security and control of access, netting of crop. Control essential during and after harvest (including seed and straw. Other factors: security of harvested seed; prevention of dispersal of seed during harvest, confirmation of elimination of released plants after harvest.

ii. Control of potential pollen recipients in the dispersal area.

31. **Pre-release survey:**

i. Dispersal area.

For release (a), the dispersal area might be within 10 m of the plot boundary.

For release (b), both of the identified hazards would need to be addressed. For (i) hazard to human or animal health - the pre-release survey should enable confirmation of the security of the proposed release site. For (ii) - possible spread of the gene - the dispersal area could be up to 100 m or more away from the plot boundary, depending on the scale of release. A large block of flowering rape could allow pollen dispersal by wind over a large area, and also be more attractive to pollinating insects.

ii. Relevant species.

For release (a), the pre-release survey should concentrate on the presence of other (mainly volunteer) potatoes within the potential dispersal area. The likely presence of adjacent potato crops or other trials within or near to the dispersal area would be particularly relevant.

For release (b), species survey should concentrate on (i) the presence of possible predators which might graze on the crop; and (ii) on the presence of compatible Brassicaceae (such as rape crops, grown for seed, volunteer and feral rape, other Brassica spp. etc.) within the potential dispersal area. It is considered unlikely that distant relatives would act as effective pollen recipients, even though they may overlap in flowering with rape. Some other Brassicas may be effective pollen recipients.
32. **Monitoring during release:**

Monitoring should concentrate on ascertaining and demonstrating that the safeguards put into place are effective.

Monitoring should concentrate on the release plot, plus the dispersal area identified in the pre-release survey, and relevant species within the area.

For release (a), only consideration of other potatoes (mainly volunteers and groundkeepers) would be relevant. If the genetically modified potato berries freely, this may create a potential problem of high numbers of transgenic seed in the area of the plot. If other potatoes are present in the dispersal area, cross-pollination could occur, possibly giving rise to transgenic volunteers with different varietal characteristics from the genetically modified parent plant (see paragraph 33).

For release (b), (oil seed rape) - relevant species to be considered are as identified in the pre-release survey. Particular attention would need to be paid to possible effects on grazing animals. Potential pollen recipients would be compatible species likely to overlap in flowering with the transgenic rape. Monitoring would also need to confirm that access to the site - either by people or potential grazing animals - is properly controlled.

33. **Post release monitoring : Example (a)**

Post-release monitoring would not be required if there is negligible potential to cause harm. It should, however be noted that:

i. volunteer potatoes have been shown to survive in the managed agricultural environment for one or more years, despite the routine application of selective herbicides during crop rotations;

ii. Genetically modified potato tubers are not at present cleared for entry into the human or animal food chains. Management safeguards are required to prevent this happening. These safeguards would include sufficient post - release monitoring to ensure that the risk of tubers from volunteer transgenic potatoes entering the human or animal food chains was negligible.
34. **Post-release monitoring : Example (b)**

The assessment indicates that continued presence of pharmaceutical rape poses a risk of harm to the environment. In addition, if sufficient numbers survive, they pose a risk of spread of the gene to compatible species and thereby increase the potential for harm.

Monitoring in such cases should therefore concentrate on the efficacy of the management safeguards put in place during and after the harvest of the crop.

i. Procedures employed during and after harvest would need to be carefully controlled and monitored: for example, harvest and collection of seed; transport to a secure store; cleaning of equipment used for harvesting; destruction of residual plant material by discing in (or alternate techniques such as desiccation and burning, or collection for autoclaving). See also paragraph 35.

ii. In the identified dispersal area, post-release monitoring would concentrate on the presence of:

   a. volunteers arising from ungerminated seed on the plot. These may be either from the original sowing, or from seed shed prior to or during harvest;

   and on

   b. possible descendants of compatible plants fertilised by pollen from the transgenic plants.

35. It is known that ungerminated rapeseed can survive in the soil for several years. As a consequence, risk management procedures should include the avoidance of any procedures that could lead to deep burial of seed on or around the plot - e.g. the use of light surface cultivation to promote germination, followed by one or more cultivation passes to destroy the volunteers - also, see paragraph 27.
An example of a pre-release questionnaire is provided below:

QUESTIONNAIRE FOR THE GENERAL RELEASE OF GENETICALLY MODIFIED PLANTS

This is a guideline to indicate the scope of the information required by the NBAC to assess an application for general release of a genetically modified plant or viable plant product in Namibia.

If the plant product is non-viable and unable to escape into the environment, no application needs to be made to NBAC for approval to import the plant product. If the plant product is viable, the applicant will need to address all the questions in this document.

The information may be submitted in any form, including that in which application has been made to any other statutory body in Namibia or elsewhere.

1. BRIEF DESCRIPTION OF THE GENETICALLY MODIFIED PLANT

Include scientific and common names of the plant, the country of origin of the plant and a description of the genetically modified trait(s).

2. GENERAL RELEASE

2.1 Detail specific instructions for the storage and handling of the plant or viable plant parts.

2.2 When will general release be implemented?

2.3 Where will general release take place?

2.4 Detail the type of environment and the geographical areas for which the plant is suited.

2.5 Who will undertake the general release?

2.6 Estimate the amount of production of the genetically modified plant within Namibia per annum, or the amount of viable plant product to be imported into Namibia per annum.
3. **DESCRIPTION OF ANY PRODUCT WHICH MAY BE DERIVED FROM THE PLANT**

3.1 Identify the part of the plant to be used for the product, the type of product, the use of the product the market sector in which the product will be marketed and the trade name of the product.

3.2 Specify the exact conditions of use of the product

3.3 Provide information on the proposed labelling of the product for marketing.

3.4 State whether the benefits of the product are available in any other non-genetically modified form. If so, state why the genetically modified form should be approved for general release when other, non-modified products are available.

3.5 Detail specific instructions for the storage and handling of viable plant products that will avoid misuse or escape of the genetically modified plant into an environment for which it was not intended.

3.6 Detail the likelihood of the genetically modified plant or its products being exported from Namibia, particularly if such export could result in the introduction of the plant into its centre of origin.

4. **BRIEF SUMMARY OF FIELD TRIALS UNDERTAKEN**

4.1 Include information on the country, year, location and the authority from whom permission was obtained to run the field trials.

4.2 Provide full data on the field performance of the genetically modified plant, including the efficacy of the introduced trait.

5. **POLLEN SPREAD**

5.1 Identify all methods of pollination applicable to the plant.

5.2 Identify pollinating agents and the distances to which pollen is known to spread.

5.3 Identify any plants in the area of general release that may become cross pollinated with the genetically modified pollen.

5.4 Describe methods to be used to prevent the spread of genetically modified pollen to wild type plants.

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Hartmann, A.M.; *Summary: Namibian Country Study on Biosafety and Biotechnology*

*Developing a National Biosafety Framework*

*UNEP-GEF Workshop, Windhoek, 3-4 February 1999*
6. **SEED DISPERAL**

6.1 If seed is to be sold, state whether the seed is hybrid.

6.2 Describe methods to be used to limit the dispersal of genetically modified seed into the environment.

6.3 If seed dispersal will occur, describe what volumes of seed are likely to be dispersed, how this seed will interact in the environment and what long term affects the seed is likely to have on the environment.

7. **VEGETATIVE SPREAD OF THE GENETICALLY MODIFIED PLANTS**

7.1 Describe methods of vegetative reproduction that are available to the plant.

7.2 Describe methods to be used to limit vegetative spread of the genetically modified plant into the environment.

8. **FOREIGN GENES AND GENE PRODUCTS**

8.1 Identify all foreign genes in the genetically modified plant.

8.2 Describe the gene products that are derived from the foreign genes.

8.3 Describe the biological activity associated with the foreign gene products.

8.4 Provide information on the rate and level of expression of the foreign genes and the sensitivity of the measurement of the rate and level. State whether expression is constitutive (continually expressed) or inducible (capable of being switched on or off by external manipulation of any sort). Are foreign genes expressed throughout the plant or only in certain organs or tissues?

8.5 Provide protocols for the detection of the foreign genes in the environment including sensitivity, reliability and specificity of the techniques.
9. RESISTANCE

9.1 Detail whether the genetically engineered plant is able to initiate resistance, in any biotic component of the environment, to any biologically active foreign gene product which it contains or produces. For example resistance to an insecticide.

9.2 Detail what methods are available to minimize the risk of such resistance developing in the environment.

9.3 Detail how resistance will be managed during general release of the genetically modified plant.

10. HUMAN AND ANIMAL HEALTH

10.1 State whether the genetically modified plant or its products will enter human or animal food chains.

10.2 Detail the results of experiments undertaken to determine the toxicity of the foreign gene products (including marker genes) to humans and animals.

10.3 If the foreign gene products are toxic or allergenic in any way, detail how the general release will be managed to prevent contact with animals or humans that will lead to discomfort or toxicity.

11. ENVIRONMENTAL IMPACT AND PROTECTION

11.1 Detail any long term effect the general release of the genetically modified plant is likely to have on the biotic and abiotic components of the environment.

11.2 Provide data and information on ecosystems that could be affected by use of the plant or its products.

11.3 Specify what effect the general release of the genetically modified plant will have on biodiversity.

11.4 Specify the measures to be taken in the event of the plant or product being misused or escaping into an environment for which it is not intended.

11.5 If the foreign genes give rise to crops resistant to agrochemicals, provide information on the registration of the agrochemicals to be used on the crop.
12. WASTE DISPOSAL

Where only a portion of the genetically modified plant will be used for the product, how will the unused plant parts be disposed of?
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