SCIENCE AND POLICY FOR MODERN BIOTECHNOLOGY IN

Biotechnology science policy nexus

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Introduction

Biotechnology is a collection of techniques that utilize biological systems or derivatives thereof to create, improve or modify plants, animals and microorganisms for specific use. Biotechnology is not new; it has been used for many centuries in agriculture and manufacturing industry to produce food, chemicals, medicines and many other products that have been of benefit in many areas including nutrition, and human and animal health. In agriculture, recent biotechnology applications include tissue culture techniques for mass propagation of disease free planting materials, disease diagnostic techniques, molecular marker techniques for characterization of germplasm to assist in plant breeding.

The most recent advances in biotechnology are often called modern biotechnology, or genetic engineering. They include a cluster of techniques that have been focused on genetic improvements of crops and production of animal vaccines.

Modern biotechnology is based on the manipulation of coded chemical information/instructions existing in the nucleus of living organisms. The products of genetic engineering are called genetically modified organisms (GMOs). The rationale of gene transfer is to use it when the desired trait is not available naturally in the target species but exist in another species; in crop species where productivity by conventional breeding have stalled and to accelerate the breeding cycle.

Typically, a breeding cycle will take six to ten generations of selection. Gene transfer can achieve this within one or two generations. The time gain can avert enormous crop losses and resulting loss of lives due to national famine. It would also accrue larger incomes to farmers and the economy. Genetic engineering has thus been applied to solve problems such as low agricultural yields and control of pests and diseases, and improvement of nutritional qualities and shelf life of foods. Nevertheless concerns have been raised about genetic modification technology, its products and its applications in various fields. Global status of commercialized biotechnology crops

According to Clive James of the International Service for the Acquisition of Agri-biotech Applications (ISAAA): the unprecedented rapid adoption of transgenic crops is a reflection of the significant multiple benefits realized by both large and small farmers in industrial and developing countries that have grown transgenic crops commercially. In 2002 the global biotech crop area continued to grow for the sixth consecutive year at a sustained rate of more than 10%. The estimated global area of transgenic crops for 2002 is 58.7 million hectares (has.) or 145 million acres, grown by between 5.5 and 6.0 million farmers in sixteen countries. During the six-year period 1996 to 2002, herbicide tolerance has consistently been the dominant trait (75%), with Bt insect resistance second (17%) and stacked genes third (8%). The two dominant crop/trait combinations in 2002 were herbicide tolerant soybean occupying 36.5 million has. grown in seven countries namely, USA, Argentina, Canada, Mexico, Romania, Uruguay and South Africa and Bt maize, occupying 7.6 million has. equivalent to 13% of the global transgenic area and also planted in seven countries – USA, Canada, Argentina, South Africa, Spain, Honduras and Germany. South Africa grew 58,000 has. of Bt white maize for food in 2002. An increasing proportion of biotech crops are grown in developing countries. More than one quarter (27%) of the global biotech crop area of 58.7 million has. in 2002, equivalent to 16 million has. was grown in nine developing countries. In 2002 over half of the world's population lived in countries where biotech

crops are approved and grown. The number of farmers that benefited from GM crops in 2002 was between 5.5 and 6 million. More than three-quarters of the farmers that benefited from GM crops in 2002 were resource-poor cotton farmers planting Bt cotton, mainly in China and in South Africa. There is optimism that global area and the number of farmers planting GM crops will continue to increase in 2003. This high adoption rate is a strong vote of confidence in biotech crops, reflecting farmers' need for and satisfaction with the technology.

Regulatory frameworks based on sound scientific principles

Global biosafety mechanisms are in place to establish that commercialized biotech crops are evaluated to be as safe and nutritious as conventionally bred crops for food, feed and the environment. Biotechnology products are widely used and consumed and have an established history of safe use since their introduction seven years ago. A number of global regulatory frameworks to ensure the safety of plant biotechnology products have been in existence for some time and efforts continue to harmonize these global regulatory processes to ensure that all regions have access to plant biotechnology products that provide benefits to growers, consumers, and the environment. Although global regulatory authorities may differ in the overall philosophical approach to regulating the safety of biotech foods, all have the common goal to protect consumers and the environment. The European Commission also recently published a report on EU biotechnology policies and launched a round table on biotechnology safety research. The Commission believes in agricultural biotechnology regulated by sound science and also stated their belief that crops and foods derived using biotechnology are at least as safe as conventional foods and are subject to greater testing and regulatory scrutiny than conventional foods. Two key questions that are addressed in the safety assessment studies conducted for biotech products include the safety of the food and feed for human and animal consumption and the safety of biotech plants for the environment. The studies that are conducted are based on scientific principles established by international experts, organizations, as well as requirements set by the regulatory authorities in the various countries around the world. The multidisciplinary safety assessment process currently used ensures that methods developed to ensure food, feed and environmental safety of commercialized biotech crops meet the standard of rigor that is accepted and endorsed by international scientific experts: this goes way beyond anything done for conventionally bred crops or other methods of food production.

Could benefits of agricultural biotechnology research reach poorer farmers?

Over the past decade there has been some advocacy of a need for a pro-poor bias in the development and dissemination of modern biotechnologies (Bunders and Broerse, 1991; Swaminathan, 1991; Lipton, 1999). There is however a question as to whether benefits of current agricultural biotechnology research will actually reach poorer farmers and consumers without major public sector intervention.

The vast majority of the world's farmers are known to have a limited level of access to external inputs or other productive resources. Resource-poor farmers, by definition, are unlikely to have easy financial access to agricultural inputs such as pesticides, fertilizers or irrigation. There are many processes, factors and socio-economic structures underlying rural peoples' poverty such as; lack of access to land and other productive resources, low purchasing power, political powerlessness, fragile environments, markets, etc (Sen, 1981). Biotechnology is one of the factors that could impact on rural poverty.

The technology could help such needs as staple crops with higher yield potential; reduction in pesticide use via insect/disease resistant crops and animals, veterinary vaccines (e.g. against brucellosis, rabies, liverfluke and hepatitis), improved nutritional composition of crops and animals, elimination of toxic substances or allergens, developing early maturing varieties, reducing post-harvest storage losses, abiotic stress tolerant crop and animals, varieties and breeds with increased water and nutrient use efficiency, enhanced nutritional and product quality through influencing quantity and quality of oil, protein, carbohydrates, nutrients and novel substances.

Scientific and technological developments in agricultural biotechnology

Biotechnology research is most powerful when it is integrated with conventional breeding or crop improvement approaches. In many countries, plant biotechnology research is being integrated with conventional plant breeding approaches wherever the technical and financial resources are available for such integration. There are already available biotechnology generated traits and processes that could facilitate pro-poor objectives if they could be transferred to the agricultural systems and crops of poorer rural communities. These include:

- Micro-propagation and plant tissue culture technology (e.g. to generate disease free plantlets of vegetatively propagated staple crops such as cassava, potato, sweet potato, etc);
- Improved fermentation technologies;
- Generation of higher micronutrient levels (e.g. vitamin A, iron, essential amino acids) in micronutrient deficient staple crops such as rice and other cereals;
- Reduced toxin levels (e.g. reduced mycotoxin contamination);
- Multiple marker-assisted selection strategies for improving agronomic traits in animal and plant varieties/breeds, including yield potential (e.g. rice and tomato);
- Development of abiotic stress tolerance genes (e.g. aluminium- and manganese-tolerant crops which can grow in acidic soils, salt tolerance and drought tolerance);
- Vaccines against human and animal diseases (e.g. cholera - toxin B, hepatitis B, herpes, rabies, Salmonella, East Coast Fever and liverfluke);
- Insect resistance (e.g. against corn borer);
- Bacterial and fungal disease resistance (e.g. against powdery mildew);
- Virus resistance (e.g. against cassava mosaic virus);
- Better crop digestibility for animals and humans (e.g. reduced or modified lignin content);
- Delayed over-ripening of fruits and vegetables (e.g. to reduce post-harvest losses); and

- Herbicide-tolerant seeds (e.g. to combat *Striga* and witchweed infestations and lower the labour burden of weeding on women and children).

The utility of plant tissue culture and micropropagation

The rapid propagation of many desirable plant varietal genotypes using plant micropropagation technology is a relatively low technology 'appropriate' biotechnology which is now delivering tangible benefits to many farmers in both developed and developing countries (van Uyen and vander Zaag, 1993; Bryan, 1988; Sasson, 1998). In addition to its rapid propagation advantages, such tissue culture can also be used to generate disease free planting materials. There are numerous examples of micropropagation initiatives which are delivering disease-free planting materials to poorer farmers. These include local level micropropagation work on, *Musa* spp and multipurpose trees in Kenya (Florence Wambugu, pers. comm.). In some instances there have been efforts to involve farmers' organizations in the design and running of such micropropagation.

Micropropagation capacity is less well developed in most African countries, yet it represents a technology which if better integrated with ongoing efforts in seed/planting material production and supply, could yield significant agronomic benefits to farmers. Plant tissue culture and micropropagation capacity if effectively coupled to local seed/planting material delivery channels could generate benefits for many resource-poor farmers. The application of such biotechnologies to local varieties and landraces of root and tuber crops could generate disease-free plantlets while helping to boost yields.

Generating new options for pest and disease resistance

Breeding for resistance to pests and diseases is a major ongoing activity for the vast majority of crops. There is a wide range of pests and pathogens for which conventional breeding has failed to produce crop varieties with durable resistance. There are also serious pests and pathogens which integrated pest management (IPM) approaches have not yet managed to address. A significant proportion of plant biotechnology is targeted at trying to develop new options for control of pests and diseases for which there are currently few control options, although most such work is concentrated on pests and diseases of major commercial crops.

Plant biotechnology could potentially have significant substitution effects in the global insecticide market. The global insecticide market is estimated to be approximately US$ 8100 million per annum (James, 1997). The development of genes (conditioning resistance against insect pests) which can substitute for some of this need for application of insecticides could have a significant impact both on the environment and insecticide sales. The source of many such genes has been the bacterium *Bacillus thuriengiensis* (*Bt*) although many other organisms are now being screened for useful genes. *Bt* has been used for decades as an insecticide spray but has had limited use outside of organic agriculture, in total accounting for less than 1% of the insecticide market. It is now estimated that US$2700 million of chemical insecticide applications could be replaced with Bt biotechnology applications, either as improved sprays or through expression in transgenic crops (Krattiger, 1997).

Other notable improvements in desirable crop traits

Hidden hunger, such as protein and micronutrient deficiencies, is a widespread and endemic problem for the worlds poorest people, especially women and children. A range of transgenic approaches have now been developed to nutritionally improve the amino acid profile of crop protein, by transferring genes encoding more nutritious proteins from other species (Molvig *et al.*, 1997).

Human disease is a major constraining factor to labour availability in many agricultural projects and to socio-economic development in general in developing countries. Lack of effective cold-storage facilities limits the efficacy of many vaccines. Vaccine production can also be expensive. Production of effective oral vaccines against major tropical diseases in transgenic plants may be an extremely appropriate and low technology means of decentralizing both vaccine production and distribution in developing countries.

Animal biotechnologies

With limited resources and an increasingly vulnerable environment, it is critically important that growth in efficiency rather than in numbers should be the dominant factor in the doubling of global output of livestock products expected to take place in the next 25 years. Improvements in efficiency arise from the development, spread and adoption of improved technologies for breeding, feeding, management, and healthcare of animals. In these respects the definition of efficiency must be production system specific.

Genetic marker technologies, such as marker-assisted selection, parentage identification, and gene introgression can equally be applied to livestock selection programmes (Davis and Deniske, 1998). Genetic maps are now available for cattle, swine, and sheep to provide the genetic framework for developing marker-assisted selection (MAS) programs.

From a public funding and regulatory (biosafety) perspective it is important to consider that not all biotechnologies generate transgenic or so called 'genetically modified' organisms (GMOs). Modern biotechnologies such as vaccine development, antibody production, immunodiagnostics, molecular genetic mapping, marker-assisted breeding and plant tissue culture are also highly useful technologies which can be applied within any particular crop gene pool to generate improved varieties which are not transgenic and hence outside the increasingly onerous restrictions of current biosafety legislation.

Ongoing debate regarding biosafety and transgenic crops

Biosafety is a term which was developed specifically in response to the ability of some modern biotechnologies to transfer useful genes across species boundaries i.e. genetic engineering as this particular biotechnology is popularly known. Biosafety assessment requires that risks, benefits and needs be given a balanced assessment in relation to transgenic organisms. Many opponents of plant biotechnology cite biosafety as the key risk based issue for the more stringent regulation of transgenic plants (Rissler and Mellon, 1996).

At one end of the extreme, environmental groups are now calling for a 5-10 year moratorium in some European countries on the planting of 'genetically modified foods'. The other end of the extreme would be no regulations regarding transgenic organisms. Much controversy and public scaremongering has been generated by anti-biotechnology groups over the 'safety' of transgenic plants in relation to their perceived negative impacts on human health or the environment.

A new development has been that many of the anti-biotechnology groups (e.g. European Greens) have now conceded that there are benefits to be derived from the application of genetic engineering for addressing human medical problems. Hence, it is the application of genetic engineering to agriculture that is now the key focus of attention of the anti-biotechnology interest groups. Civil society perceptions of agricultural biotechnologies in many countries are now distorted because of highly polarized lobbyist campaigns between the biotechnology industry on the one hand and anti-biotechnology groups on the other. The independent presence of public sector agricultural biotechnologists and scientists has, on any significant scale, been lacking from this ongoing polarized debate (Butler, 1999a). Similarly, many membership-based organizations which are more broadly representative of civil society such as trade unions, producers organizations and farmers' organizations have also not been involved in these debates.

Agricultural and food policy makers involved in developing regulations regarding biosafety of transgenic plants should carefully assess what role transgenic research is to have in future food production (both for domestic and export purposes) in their countries. The rapid escalation of increasingly stringent biosafety regulations regarding transgenic plants (or food), in the absence of any scientifically proven generic risk, is most likely to limit any application of transgenic research to meeting either staple food production or poverty alleviation needs. If transgenic options are not envisaged in agriculture it is the responsibility of policy makers and regulators to identify what types of agricultural research is going to meet food and livelihood security needs. In effect, the blanket adoption of a 'no risk' precautionary principle risks an imbalance between the avoidance of harm and the achievement of a positive good.

Biosafety regulations

The issue of who decides what level of risk farmers/consumers should be exposed to is also an important consideration for any countries development of biosafety regulations. This is an area where promoting the greater participation of organizations who actually represent the needs of different groups of farmers and/or consumers could be most appropriate. Many of the most vocal environmentalist or consumer organizations may not actually be very representative of the majority of farmers or consumers needs, especially poorer farmers.

The absence of a functional biosafety review system may negatively affect the local development and importation of new biotechnology products, and therefore farmers' access to potentially useful germplasm and technologies. For instance, the Cassava Biotechnology Network has been developing transgenic lines which have a higher tolerance to cassava mosaic virus, a trait that is critical to small-scale farmers' situations in Africa and in vast poor areas of South America. When the projects were initiated in the early 1990s, it was planned

to field-test the transgenic plants in South America and Africa, in countries where cassava is a staple crop and a national priority. Delays have occurred in the implementation of biosafety regulations in countries where the tests would have been made. It now appears possible that the first field tests of transgenic cassava will be in collaboration with one or more biotechnology research institutes in Southeast China. Yet the transgenics are derived from parents adapted to South America and Africa parents, and the target traits are not high priority for China. The absence of biosafety regulations in the target countries will create a delay in developing the most suitable research products and getting them in the hands of target farmers.

On the other hand, a very stringent biosafety review system can also delay or prevent farmers' access. Indeed, the cost of a regulatory system for biosafety within any one country is an important factor which has implications for determining which farmers will ultimately have access to biotechnology products. High regulatory costs will have an effect on what transgenic traits are ultimately to reach farmers and will further bias research towards wide rather than specific adaptation (Barton *et al.*, 1997). High regulatory costs will select for only those traits which represent the greatest commercial gain to the developer of the variety. Such regulatory costs can be high - In the USA it can cost US$1 million to get a plant biotechnology product through the regulatory system. If such expensive regulatory systems are used in developing countries the cost will either bias all transgenic research towards meeting the needs of the wealthier sectors of society or transgenic plant biotechnology will remain primarily at the research stage.

Over-stringent biosafety regulations are likely to disproportionately benefit larger companies over smaller companies or public sector bodies by acting as significant `barriers to entry' to certain markets. The higher the regulatory hurdles the higher the chance that competition will be between companies and that any benefits of biotechnologies will not reach poorer farmers.

Labelling transgenic foods

Consumers have a definite right to information and hence choice regarding which foods they purchase or eat. However, consumer information is based on the premise that the information provided to the consumer is of utility to the consumer in making an informed choice. For instance, knowledge of the biological or species composition of foods will be of use to those who suffer from allergies to particular foods or compounds. The USA requires labelling of transgenic foods that are substantially different from their unmodified counterparts, including foods that could contain a potentially allergenic compound such as a peanut protein or glutenins (FDA, 1995). Indeed, it is questionable whether the label `genetically modified' conveys any information of utility to the typical consumer in terms of making an informed choice based on what is currently known about transgenic food (Reid and Hendricks, 1994; Miller *et al.*, 1997; Anon, 1999b).

Even though process-based labelling of transgenics as 'genetically modified' makes little scientific sense, it is probable that such labelling will become widespread. Product-based labels indicating the biological composition (e.g. species of origin, biochemical types and levels) may have been more informative to consumers. Process-based labelling of transgenic

foods will have important 'knock on' effects which agricultural and food policy makers should carefully consider in developing biosafety and labelling regulations that could benefit farmers and consumers, especially poorer societal groups.

Ongoing scientific and policy developments regarding biosafety

Base-line studies are being established for conventional agricultural practices, against which risk analysis of transgenic crops can be conducted. Whether a particular type of risk has to be assessed in a particular location or context will largely depend on the risk itself. Hence, there may be possibilities for international harmonization of food safety testing of transgenic varieties, whereby if they have not proved detrimental to human health in one country, they are unlikely to do so in another country. Such risks can be assessed based on what is known about human dietary biology regarding conventional foods.

Strict application of the so-called 'Precautionary Principle' regarding GMOs may be counter-productive to social and economic development. A good retrospective example of such potential counter productivity is the eradication of poliomyelitis. The polio virus has been responsible for paralyzing between 10 and 20 million people world-wide. In 1961 Albert Sabin developed the live, attenuated oral polio 'Sabin' vaccine which can be easily orally administered by an untrained volunteer and produces high levels of immunity against the disease. In 1996, more than 420 million children - almost two thirds of the world's children under five - were vaccinated against polio. The number of cases of polio world-wide continues to drop e.g. from 350,000 in 1988 to about 35,000 in 1998. As a result of these WHO-UNICEF-led worldwide vaccination efforts using the Sabin vaccine, it is likely that polio will be globally eradicated as a disease early this century. Eradicating polio will globally save an estimated $1.5 billion in immunization, treatment and rehabilitation every year (Schlein, 1998). However, the Sabin vaccine is a so-called 'attenuated' virus that is a mutant, no longer pathogenic, of the live polio virus. When the RNA coding sequence of the Sabin vaccine was determined and compared to that of the live polio virus, it was found that only two base change mutations in the genetic code were involved. Because of the high error rates of replication of RNA viruses, in theory such a mutant could revert to the live virus within 48 hours. If this knowledge had been available in 1961 and a strict 'Precautionary Principle' had then been applied it is likely that the Sabin vaccine would not then have been applied to the eradication of polio. While revertants of the polio vaccine to the live polio virus do occur in approximately 1 in 3 million cases, it is fortunate that, for the vast majority of people, 48 hours is sufficient for the polio vaccine to trigger a highly effective immune response. Strict application of the 'Precautionary Principle' would suggest otherwise (Eigen, 1995).

National and international biosafety policy development

Policy decisions taken in regard to biosafety regulations may have long-term implications for the sustainability of agriculture and food security. In particular, policy makers should now realise that long-term negative implications for agriculture and food security can equally arise from having biosafety regulations which are either too lax or too stringent. If any countries

expect over the long term to benefit from modern biotechnologies in their agriculture and food sectors, they will have to give serious consideration to the drafting of biosafety regulations which are tailored to meet their socio-economic needs.

Intellectual property rights and related developments

Intellectual property rights (IPRs) represent a useful means by which private investment in research and development can be promoted. IPRs provide commercial incentives for research and development activities by prohibiting direct copying without permission (e.g. the payment of a royalty). The concept is that the inventor or other creator cannot compete with a copier who shares none of the development costs. In return for the risk of such investment, the IPR owner obtains for a limited period (e.g. 20 years) the right to use the intellectual property exclusively, assign ownership, license it, or not use it at all. The IPR owner can enforce these property rights if others misappropriate or otherwise infringe the protected intellectual property. In a social sense, intellectual property rights represent a means to promote commercially relevant innovation, and are not an end in themselves (Leisinger, 1996).

When considering the incentive effects, it is important to recognize what privileges IPR do and do not provide. They do not assure a return; indeed only up to 15% of patents are ever commercialized. Hence, predicting the level of future use from the simple act of filing a patent is a difficult if not impossible exercise. IPRs do not necessarily permit the use/practice of the creation as this is often controlled by other regulations (e.g. biosafety) or even other patents. Primarily, they allow the right to exclude others from use, what can be called negative rights. All financial rewards must typically come from market sales although social rewards might accrue from licensing at lower rates to non-commercial users. For most IPRs, key factors such as the breadth (scope) of protection are critical in determining the commercial value of the IPR. IPR legislation is national law, applying only in those countries where it is available and has been granted.

In the agricultural research arena, both scientific knowledge, and its commercial applications are increasingly becoming proprietary. Proprietary rights over agricultural biotechnology products and processes are being claimed by both private firms and an increasing number of public institutions. Such rights include trade secrets, patent rights, plant varietal protection (PVP), and contractual rights arising from the use of material transfer agreements (MTAs) (TAC, 1998). How regulations, policies and incentives regarding public sector funding of agricultural biotechnology research are framed by governments will have a major impact on whether agricultural biotechnologies can have a beneficial impact upon global food and livelihood security. In particular, it will be increasingly important for governments to more specifically identify whom the primary beneficiaries of public funding are, what the purposes of such funding are and what stakeholders will have real access to any useful biotechnologies generated from public funds.

Biotechnology policy formulation process

The first step in the biotechnology policy formulation process is to identify and set priorities for the nation. The priorities identified should address significant constraints to productivity,

offer a comparative advantage for the application of biotechnology and demonstrate that there is need for biotechnology products. The priorities should be linked to national development objectives so that they are implemented in the context of the national policy setting, organizational options, and financing available.

Priority setting in biotechnology is usually complicated by budget constraints hence it is important to have a strong political buy-in so that policy makers and politicians can give higher financial priority to biotechnology than other pressing needs.

Public policy setting

There are several public policy issues that affect the options available for undertaking biotechnology research and development. These include public perception, biosafety, intellectual property rights, organizational options and financing.

Public perceptions

Public education, including the education of technology users and those in charge of technology dissemination, is a critical component in the transfer of technology from the laboratory to the field. This is particularly true of products involving new technologies such as recombinant DNA techniques. Here, initial public perceptions about product safety and efficacy may have far-reaching implications for further technological advancement. Public opinion can affect the processes involved in product development and can be a powerful force in the initiation of good developmental practices for research. Initial "familiarization" efforts conducted by commercial entities in the United States have provided a better understanding of biotechnology testing at the local, regional, and national levels. Many of these efforts have been product or test specific and designed to educate the public on issues and questions regarding perceived safety issues surrounding new technologies. Such efforts to increase the public's understanding of new approaches, coupled with a demonstrated safety record, will help reduce the "familiarity gap," which often occurs with the advent of new technological innovation. This, in turn, helps minimize regulatory hurdles. Scientists at the research level need to help structure appropriate guidance so that familiarization of the public, and hence of national decision makers, occurs in conjunction with new research developments. Such a process reflects the fact that biotechnology is part of the agricultural research continuum. Scientists are made aware of requirements for information to satisfy questions of safety. As such, scientists and public officials provide decision makers with information that better prepares them for making informed decisions regarding public perception.

Developing effective biotechnology products, which address recognized priorities, provide needed agricultural inputs, and present a comparative advantage over products already available to farmers, will do much to bolster public confidence. An essential factor in building public familiarity with biotechnology research will be the technical excellence and improvement offered by each research innovation.

Biosafety considerations

Is there a review mechanism in place to ensure the safe and efficacious application of biotechnology? If not, the formation of a national biosafety committee is desirable. However, the relevance of such a committee depends on the degree of local understanding

and competence in biosafety (Plucknett et al. 1990, Persley et al. 1992). Institutional expertise can also play an important role in increasing national programs' opportunities to collaborate with programs that are applying new techniques and providing products of genetic engineering. If national safeguards have not been established, the testing of new genetic material may be limited in scope and effect.

Intellectual property rights

The availability of IPR protection can serve as a means to increase private-sector inventiveness, to gain access to proprietary technologies, and to stimulate public-private collaboration. It can also be demanding in terms of the requisite legal expertise and the costs involved in filing for such protection. For example, in the United States, $10,000 to $15,000 is required to complete one patent application.

A strong public-sector effort in biotechnology is needed. The public sector alone may not be sufficient to meet future national agricultural and economic needs. Combined public- and private-sector efforts are more likely to satisfy national research needs. Decisions on biotechnology and IPR are guided by these factors, as well as by national technology objectives including the extent to which national science and technology policy is increasing local innovative capacity, and different means to expand acquisition and transfer of technologies (van Wijk et al. 1993).

Integration and Organizational Options

After setting priorities, organizational options should be reviewed. This means reviewing the institutional base required to initiate biotechnology research. One question requiring resolution is whether expertise in biotechnology should be added to existing programs (such as plant breeding) or if future research is better placed in a new institute. As far as plant improvement is concerned, biotechnology presents a complementary set of tools not to be isolated from breeding, but rather to become a part of it. For new facilities, high start-up costs should be expected, as well as long-term support for recurrent costs. Particularly important are needs for backup generators to ensure electrical supply, service agreements for specialized equipment, and ready access to growth chambers and greenhouses. Many of these items are already in place in conventional research programs. In such cases the integration of complementary molecular technologies with conventional programs should not be difficult. Thus, biotechnology becomes an extension of the scientific base for agricultural research, requiring institutional adjustments and investments. Establishing a separate biotechnology center can undermine the morale of the plant scientists not based at such a facility. This is especially true if different salary scales exist for scientists trained in advanced molecular biology. Biotechnology products reach consumers only through conventional development and release. Therefore, it is essential that a strong conventional technological base be maintained and supported.

Financing Biotechnology Initiatives

Decision makers at the national level may establish biotechnology policies. However, they are often unable to provide secure funding to address their priorities. For biotechnology to achieve targets of national priority there is need to estimate correctly and provide total costs and financing. The participation of management in decision making and planning can help define realistic needs for additional resources and recurrent costs. Funding approaches usually mix limited national program and institutional support with financing from

international donor agencies, development loans, international biotechnology programs, competitive grants, and other sources. National finance, planning, and technical managers are increasingly aware of the international base of financial support available for biotechnology and its increasing significance among donors.

Appendix 6: Science and Technology in Malawi: The role of NRCM in Biotechnology issues

1.0 Background and Historical Context

The importance of science and technology was recognized by the Malawi Government as early as the 1970s when it established the National Research Council of Malawi in 1974. The decision to establish the NRCM was, partly prompted by the attendance by Malawi of the Conference of Cabinet Ministers responsible for the Application of Science and Technology to Development in Africa (CASTAFRICA I) held in Dakar, Senegal from 21 to 30 January, 1974. At that conference it was observed that Research and Development and scientific and technological services are a source of momentum for development and that to turn them into best account, each country should possess its own scientific and technological base capable of generating and accelerating this momentum. It was further noted at CASTAFRICA I that, any nation, however underdeveloped or small in population, must have a national science and technology policy.

While the establishment of the NRCM may be linked to the results of CASTAFRICA I, Malawi never prepared a coherent national science and technology policy until 1990 when the first National S&T Policy was developed and adopted in 1991. In undertaking this exercise, Malawi sought to address the problems that are commonly encountered in the development of science and technology in Africa identified by CASTAFRICA II held at Arusha, Tanzania from 6 to 15 July, 1987. The 1991 National Science and Technology Policy outlined broad strategies to address these problems. It is widely accepted, however, that the policy has not been implemented fully and some of the reasons that have contributed to this situation include:

- *The country's pluralistic approach in the management of science and technology;*
- *Lack of integration of the policy in overall development plans of government;*
- *Lack of human, financial and material resources; and*
- *Lack of necessary supporting legislation.*

Each sector decides the level of research capacity to establish, the issues to be addressed, the degree of consultation to be followed, and the levels of funding for Research and Development without the benefit of a coordinating mechanism. The NRCM was therefore established to play such a coordinating and developmental role. In performing its role, the NRCM experiences two main obstacles that are always present in all scientific systems in early stages of development.

The first and probably most important obstacle is the inability to coordinate and direct research without the power to influence budgetary considerations. The issue is not unique to NRCM. The National Research Council of Canada in the 1940s and 1950s battled with the same issue and the resolution was the establishment of its own research performing institutions and the abandoning of its coordination role. The second obstacle has been the instability and uncertainty surrounding the institutional aspects of NRCM. The NRCM was established with a Secretariat in the Office of the President and Cabinet (OPC). Later, NRCM's activities were merged with those of the Environmental Unit from the then Ministry of Forestry and Natural Resources in 1988. In 1991, the Secretariat was elevated to a full Department. In September 1994, the Government elevated the Department to a full Ministry called the Ministry of Research and Environmental Affairs. The NRCM was reconstituted in July 1997 following the restructuring of the Ministry of Research and Environmental Affairs and reverted back to OPC as a department pending dissolution. In the year 2000 there was restructuring of Ministries and a Ministry of Education, Science and Technology was born. This development however, did not clarify the position of the NRCM as such the NRCM had a dual reporting system where Ministerial guidance was provided by the Minister while all administrative and financial provisions of the NRCM came from OPC. This dual allegiance of the NRCM has brought some misunderstandings, sometimes at the expense of progress.

2.0 Current Policy and Legislative Initiatives

As a Nation, a number of policies and legislative initiatives have been developed and adopted. These include:

- The Malawi Vision 2020 of 1999
- Malawi Poverty Reduction Strategy Paper of 2001
- National Science and Technology Policy of 2002
- Science and Technology Bill of 2002

2.1 Malawi Vision 2020

The Malawi Vision 2020 states that ***"By the year 2020, Malawi as a God-fearing nation will be secure, democratically mature, environmentally sustainable, self reliant with equal opportunities for active participation by all, having social services, vibrant cultural and religious values and being a technologically driven middle –income economy".***

The Vision 2020 recognizes the importance of a science and technology led development and identifies the need to:

- improve science and technology education, training and culture
- promote and commercialize research and development
- promote the transfer and adapt new and emerging technologies
- promote environmentally-sound technologies
- achieve effective science and technology
- promote use of information and communication technologies

2.2 Malawi Poverty Reduction Strategy Paper

The Malawi Poverty Reduction Strategy recognizes that science and technology contributes significantly to socio-economic development. It also indicates that Malawi is characterized by low application of science and technology in socio-economic development planning, and that this low content of science and technology in socio-economic development programmes is a barrier to economic growth leading to the high level of poverty among Malawians. The MPRS further places science and technology as a cross-cutting issue that ought to be integrated into all sectors for an effective poverty reduction process.

2.3 The National Science and Technology Policy

2.3.1 Goal and General Objectives

Malawi has developed the National Science and Technology Policy which was endorsed by Cabinet in August 2002. The policy sets out objectives and strategies for building science and technology capacity in this country. The overall policy goal of the National Science and Technology Policy is to attain sustainable socio-economic development through the development and application of science and technology in order to improve the standard and quality of life of all Malawians. The general policy objectives are:

- Establish and strengthen national capacity to research, evaluate, select, acquire, adapt, develop, generate, apply, and disseminate technologies
- Develop and raise the national productive capacity and improve competitiveness through the efficient application of technologies
- Promote and develop traditional, endogenous, new and innovative technologies
- Create knowledge and S&T awareness to improve and develop the scientific and technological culture of Malawians

2.3.2 Policy strategies

The Policy has recognized all the emerging technologies such as Information and Communication technologies, and Biotechnology, as pervasive and converging technologies.

(a) Biotechnology

Biotechnology is a collection of techniques that utilize biological systems or derivatives thereof to create, improve or modify plants, animals and microorganisms for specific use.

Modern biotechnology on the other hand refers to the most recent advances in biotechnology and sometimes referred to as genetic engineering. They include a cluster of techniques that have been focused on genetic improvements of crops and production of animal vaccines. Modern biotechnology is based on the manipulation of coded chemical information /instructions existing in the nucleus of living organisms. The products of genetic engineering are called genetically modified organisms (GMOs). The rationale of gene transfer is to use it when the desired characteristic (or trait) is not available naturally in the target species but exist in another species.

The Policy has spelled out strategies aimed at developing biotechnology in Malawi as follows:

1. Establish and strengthen centres of excellence in specific areas of biotechnology
2. Increase awareness in biotechnology and its potential impact on socio-economic development through demonstration and training centres;
3. Intensify the development of human resource capability in biotechnology;
4. Establish a national programme of action for promotion of the adoption of biotechnology;
5. Establish capacity to monitor and evaluate biosafety issues in the economy; and
6. Establish programmes of international cooperation in biotechnology.

2.4 Science and Technology Bill (2002)

The Science and Technology Bill is the main legal instrument that aims at facilitating implementation of the National Science and Technology Policy. Its main thrust is to establish the National Commission for Science and Technology and a Fund for the Advancement of Science and Technology in Malawi. The National Commission for Science and Technology will be a governmental organization that will be vested with overall responsibilities of promoting the development and application of science and technology in this country. The Fund will be the main window that the Commission will be using for supporting science and technology programs.

In relation to biotechnology the Science and Technology Bill (2002) "Clause 37" makes it a requirement for anybody who wants to engange in biotechnology to seek consent from the Commission. The clause above reads: ***Notwithstanding the provisions of the Biosafety Act [No. 13 of 2002] and any other Act, no person shall engage in any matter related to biotechnology without prior consent of the Commission.***

3.0 Coordination of Science and Technology Issues

The NRCM coordinates science and technology issues through subject specialist technical standing committees. In all, the Council has nine committees, namely:

- Committee on Scientific and Industrial Research and Development (CSIRD)
- Genetic Resources and Biotechnology Committee (GRBC)
- Legal and Patenting Policies Committee (LPPC)
- Agricultural Sciences Committee (ASC)
- Research Programmes Committee (RPC)
- Building and Construction Research Committee (BCRC)
- National Health Sciences Research Committee (NHSRC)
- National Documentation and Information Coordinating Committee (NADICC)
- Science Competitions Committee (SCC)

The membership of the committees and the terms of reference are in the annex. The GRBC and NHSRC have a very direct bearing on biotechnology and have been briefly highlighted below.

3.1 Genetic Resources and Biotechnology Committee

The National Research Council of Malawi has nine subject specialist committees and one of these is the Genetic Resources and Biotechnology Committee (GRBC). The GRBC among other things promotes and encourage endogenous development of biotechnology in areas where Malawi has a comparative advantage and also fosters the dissemination of information on trends in biotechnology.

3.1.1 GRBC Terms of Reference

- Institute measures harmonious with relevant guidelines available in the country to ensure that collection of Malawi's genetic materials does not lead to loss of Biological Diversity and / or Government revenue;

- Ensure that the importation of genetic resources (including genetically modified living organisms) and germplasm does not adversely affect the conservation and sustainable use of Biological Diversity;

- Ensure that exchange of genetic resources and germplasm is done in such a way that Malawi benefit economically from whatever is exported;

- Encourage the establishment of gene banks and genetic data banks (*in-situ and ex-situ*) and formation of strong linkages with the banks including the SADC gene Bank;

- Advise the government on which of the country's genetic materials should be protected against detrimental use by researchers, collectors and traders;

- Foster the dissemination of information on trends in biotechnology;

- Keep abreast with the national, regional and global trends in intellectual property rights and trade;

- Ensure that expatriate researchers work closely with competent Malawian researchers;

- Encourage and promote endogenous development of biotechnology in areas where Malawi has comparative advantage.

3.1.2 GRBC Membership

The membership of the Genetic Resources and Biotechnology Committee is broad based and the National Research Council of Malawi is only a Secretariat to this committee. The following institutions are represented in the committee:

- Bunda College of Agriculture, (Chair)
- Environmental Affairs Department
- Forestry Research Institute of Malawi
- Museums of Malawi
- Fisheries Department
- Department of Agricultural Research Services
- Malawi Bureau of Standards
- Malawi Revenue Authority

- Malawi Industrial Research and Technology Development Centre
- Department of Animal Health and Industry
- Monsanto Malawi Limited
- Department of Parks and Wildlife
- National Herbarium and Botanical Gardens of Malawi
- Biology Department, Chancellor College
- Malawi Plant and Genetic Resources Centre, Chitedze Research Station
- Biotechnology-Ecology Research and Outreach Consortium (BioEROC)
- Centre for Environmental Policy and Advocacy
- The Malawi Police Service
- Immigration Department

3.2 National Health Sciences Research Committee

The Malawi Mission to the United Nations requested Malawi to provide its position on human cloning. Ministry of Foreign Affairs and International Cooperation being cognizant that it was a science and technology issue asked NRCM for advice. NRCM referred the issue to the NHSRC. The position of the committee was as follows:

- Human reproductive should not be allowed
- Germ-line cloning for human enhancement should also not be allowed
- Malawi recognizes the potential benefit in therapeutic cloning. However, research and therapeutic activities should be carefully controlled. To this effect the following were recommended:
  (a) Human embryos should not be created for research /therapeutic purposes
  (b) Donation of human egg for commercial purposes should not be allowed, while as compassionate donation of human eggs to a known recipient should be considered on a one to one basis

- Although human cloning technology has not yet been introduced in Malawi, the Malawi Government requests the United Nations to assist it in developing capacity for monitoring human cloning activities
- In the absence of internationally recognized policy and legal frameworks on human cloning activities, the Malawi Government requests the United Nations to facilitate the development of the same

4.0 Conclusion

Biotechnology cuts across many sectors and is hence pervasive which results in convergence of sectors. It is therefore important to have a proper institutional framework for coordination of biotechnology issues to ensure that the country derives maximum benefit from this emerging technology. It therefore calls for stakeholders and players in a technology such as biotechnology to appreciate each others roles, consult each other and indeed properly coordinate their activities in order for them to reap the benefits from their efforts. This is why, institutions with a coordinating mandate such as the NRCM, ought to take a

lead in facilitating the cause of biotechnology in a systematic manner. The need for a biotechnology policy therefore is but a tool that shall facilitate this coordination.

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