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# Biotechnology and its Implications for ACIAR

**Vimala Sarma**

## Foreword

Biotechnology comprises a powerful set of modern biological tools and techniques with the potential to contribute to global food security. The effective application of biotechnology by ACIAR to achieve program objectives raises issues which need examination and discussion.

Fortuitously, Dr Vimala Sarma, a participant of the Executive Development Scheme of the Public Service Commission, and previously Secretary of the Genetic Manipulation Advisory Committee, joined ACIAR in 1994 for her third placement under the Scheme. As part of her activities in ACIAR, she was given the task of examining current developments in biotechnology and their relevance to ACIAR's activities, discussing issues arising from them, and formulating recommendations. This report represents her informed assessment of the issues, their significance for ACIAR, and possible mechanisms to address them.

The options and recommendations contained in this report are an important contribution, and I hope will stimulate further debate on biotechnology issues within ACIAR, with our partners, and perhaps more widely in the international agricultural development scene.

ACIAR's country partners are developing their positions with respect to a number of important aspects of biotechnology including intellectual property rights and biosafety, and ACIAR needs to be responsive to evolving policy on these issues, not the least being partner country responses to obligations under the Biodiversity Convention. The significance of the links between the Biodiversity Convention and biotechnology issues are increasingly recognised in the international arena. For example, developing countries may support international protocols which may result in conditions being attached to endemic germplasm prospecting by developed countries, aimed at germplasm enhancement through biotechnology.

ACIAR also needs to consider its own responses to the issues raised in this report, particularly in the light of the developing Australian position on biotechnology issues. Some of these issues have wider implications which may need to be considered as ACIAR develops its own policy position. ACIAR's policy response to biotechnology developments needs to be dynamic, in the light of rapidly changing technological, social and economic circumstances. Thus ACIAR will be better equipped to make the most effective use of biotechnology, as its multi-faceted dimensions unfold in the global arena, as well as domestically.

ACIAR is grateful to Dr Sarma for this useful and timely contribution to the development of ACIAR's thinking on the role of biotechnology in our programs. ACIAR would also like to acknowledge the favourable and helpful comments of Professor Bruce Holloway of Monash University, and Dr Elizabeth Heij of the Division of Horticulture CSIRO, who reviewed early drafts of this report.

DI Bevege  
Acting Director  
August 1995

## **Terms of Reference**

**1. Taking into account ACIAR's statutory functions, mode of operation and its expanded mandate *post* its 1992 'sunset review', identify the main issues relating to the use biotechnology in agricultural research funded through ACIAR's bilateral and multi-lateral programs. In particular, identify:**

- applications in biotechnology relevant to ACIAR's research program disciplines;
- constraints (including institutional and policy constraints) and opportunities for collaboration in biotechnology between Australia and its mandate countries;
- the strengths and weaknesses of Australia and its partner countries in the application of biotechnology, noting national priorities, programs and capabilities;
- policy issues, including intellectual property rights, biosafety, biodiversity, and policy on funding biotechnology projects undertaken by the International Agricultural Research Centres; and
- training and research capacity building opportunities in biotechnology, taking into account the role of other agencies and donors.

**2. Consider ACIAR's options for appropriate policy and procedural responses to the issues identified, including training for ACIAR staff.**

**3. Formulate recommendations arising from the options to enable ACIAR to address institutional and policy constraints, and to maximise opportunities for successful bilateral and multi-lateral collaboration in agricultural research applying biotechnology.**

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# Biotechnology and its Implications for ACIAR

## 1. Executive Summary and Recommendations

BIOTECHNOLOGY is a set of modern biological research tools and technologies which have been widely adopted in research institutions in all developed countries including Australia. These biotechnologies can achieve objectives in agricultural research, as in all other areas of biological research. Biotechnology can thus play an important role in development objectives for agencies involved in international agricultural research.

This paper reviews the current status of biotechnology in agricultural research from the viewpoint of an Australian Government agency namely the Australian Centre for International Agricultural Research (ACIAR) which funds collaborative agricultural research in countries within its geographic mandate. It discusses existing issues accentuated by the use of biotechnology, and the policy implications arising from these issues. It focuses on the mode of operation, internal processes and procedures of ACIAR, in order to identify policies and procedures to address the issues.

### Significance of Biotechnology for ACIAR

Biotechnology has the potential to contribute to the objectives of all ACIAR's bilateral programs. In order to make the best choice of methods that will achieve these objectives, ACIAR needs to gain an increased appreciation of the scope, capabilities and limitations of current developments in biotechnology.

#### *Recommendation 1*

*That ACIAR invite working scientists from different disciplines to explain new developments in biotechnology in a series of in-house technical seminars.*

#### *Recommendation 2*

*As biotechnology provides a set of tools to achieve research objectives, it has the capacity to*

*contribute to all program areas, and could be integrated into projects where its use is the best way to achieve the objectives of the project. It can complement traditional research methods, and is most successful when augmenting pre-existing research strengths in the partner country.*

#### *Recommendation 3*

*That ACIAR consider acquiring, developing, or contracting sufficient expertise to assess the feasibility-of-concept in biotechnology projects, and to advise on issues such as biosafety and the relative capabilities of particular institutes to carry out biotechnology projects at the in-house review process.*

### Policy Issues Associated with Biotechnology

The most important policy implications arising from biotechnology for ACIAR's bilateral programs arise from issues surrounding the equitable allocation of intellectual property rights (IPR) and biosafety. Proposed projects in ACIAR go through a thorough development stage (Phases 1-4) where such issues could be taken into account. A number of steps could be taken to ensure that the research arising from the use of biotechnology, if commercialised, is accessible to ACIAR's partner countries involved in the research, and that IPR is equitably distributed and managed.

#### *Recommendation 4*

*If there is potential for a marketable product to be developed from the research, where feasible, an Australian company capable of marketing the product overseas might be associated with the project from its inception, and efforts be made, to secure appropriate proportional (or matching) funding from the company.*

#### *Recommendation 5*

*That ACIAR's policy of the equitable allocation of intellectual property rights (IPR) is appropriate*

for biotechnology, and that the Phase 2 proforma be amended to seek a statement on the allocation of IPR from the commissioned organisation at that stage of project development. ACIAR could examine the mechanism of compulsory licensing arrangements for spillover benefits to other developing countries which might otherwise find it difficult to access the product.

The biosafety of research arising from genetic manipulation research is also an important consideration at the project development stage. Genetically manipulated constructs arising from the research need to be assessed and field-tested so that any potential hazard is identified and the trial monitored. There are ethical concerns with animal experimentation, and consumer acceptance and regulation of genetically manipulated foods, which raises issues that require appropriate criteria to be met at the project design stage. It is not ACIAR's role to conduct such assessments but there might be awareness of the criteria to be met, and the responsibility for undertaking clearances should be identified and clarified in the project documentation.

#### *Recommendation 6*

*ACIAR's Research Program Coordinators should be aware of the criteria for biosafety and food safety assessment at the stage when the genetic construct is planned, if a genetically manipulated organism is contemplated in the proposal.*

#### *Recommendation 7*

*The project pro-forma at the Phase 2 stage of project development should require explicitly, that the Australian project leader take responsibility for obtaining any necessary approvals, including ethical approval for animal experimentation, from institutional ethics committees within the Australian commissioned organisation, and for any clearances for genetic manipulation work falling under the guidelines of the Genetic Manipulation Advisory Committee (GMAC).*

As the regulatory systems in ACIAR's partner countries for biosafety assessment are variable, ACIAR would need to formally notify its partners of any proposed release of genetically manipulated organisms associated with a project, and where there are no national assessment procedures, further measures may be necessary to safeguard ACIAR's position.

#### *Recommendation 8*

*If the field trialing of a genetically manipulated organism (GMO) in a partner country is proposed in a project, ACIAR should formally advise the*

*relevant Ministry in the partner country of the fact prior to the release of the GMO so that any necessary clearances can be obtained. This notification can be undertaken with the contractual documentation for the project, or subsequently, if the release was not foreseen at the inception of the project. Where feasible, GMAC advice on the monitoring requirements of the trial should be sent to the Project Leader in the partner country.*

#### *Recommendation 9*

*Where it is clear that the partner country has no regulatory or advisory system for the assessment of the environmental release of genetically manipulated organisms, the advice of the in-house biosafety committee of the relevant international agricultural research centre could be sought, if such a centre exists in that country. If not, ACIAR may need to assume the responsibility for commissioning such assessment in the partner country.*

### **Multilateral Issues**

Australia has signed and ratified the Biodiversity Convention and currently domestic discussions are underway on access to Australia's germplasm, and on Australia's position on the need for a biosafety protocol. Any decision on the need for a protocol under the Convention will have an impact on ACIAR's activities. Multilateral issues arise from the use of biotechnology but these issues are not confined to biotechnology only. These issues relate to collection, and safe transfer and exchange of germplasm, including germplasm improved by the use of biotechnologies. In order to implement and take into account Australia's obligations under the Convention, these measures are recommended:

#### *Recommendation 10*

*Where it is envisaged that germplasm is to be collected in a project, the Memorandum of Understanding (MOU) for the project should foreshadow this, and seek approval from the national government of the partner country under mutually acceptable terms.*

#### *Recommendation 11*

*That liaison with the Commonwealth Department of Foreign Affairs and Trade be strengthened so that ACIAR is represented on relevant Australian Government inter-departmental committees set up to consider Australia's obligations under the Biodiversity Convention, and on any international expert meetings related to the Convention.*



ACIAR's Act was reviewed after 10 years of operation in 1992. As a result of the 'sunset' review, ACIAR was given the responsibility for Australia's allocation to the network of International Agricultural Research Centres (IARCs). IARCs serve as important repositories of germplasm of agricultural significance, but there is an unmet need for the funding of research associated with *in situ* conservation of germplasm in developing countries. ACIAR seems best placed to take up this role as, among relevant Australian government agencies, ACIAR has both the technical and financial resources for undertaking this aspect of Australia's obligations under the Convention.

#### *Recommendation 12*

*That in allocating funds to the International Agricultural Research Centres (IARCs), ACIAR give consideration to funding projects in developing countries involving research associated with the conservation of germplasm, including in situ conservation, so that the international research community may be more likely to be granted continued access to endemic germplasm.*

IARCs are actively embracing biotechnology and their projects and programs need to be co-ordinated with those of ACIAR's so that there is no duplication of research effort.

#### *Recommendation 13*

*That ACIAR be aware of the programs of the IARCs and of new projects, including biotechnology projects, so that there is no duplication of research effort, but a complementarity is achieved to add value to the work of IARCs.*

### **Training and Capacity-Building**

All ACIAR's partner countries with any significant biotechnology research capability have identified the lack of trained personnel, research infrastructure and expertise as the major constraint in their biotechnol-

ogy programs. The most important role that ACIAR can play in assisting biotechnology research in developing countries is capacity building and training. Australia is well placed to fulfil this role because of its strengths in the quality of its scientists and their expertise. Australia can also offer advice and training on biosafety assessment. In the area of biotechnology training, there are a number of other players in ACIAR's geographic mandate countries, and it is important not to duplicate courses but to add value to existing courses.

#### *Recommendation 14*

*That ACIAR consider funding Australian experts as resource persons in biotechnology training programs and courses organised by other donors in the region when they meet ACIAR's training objectives.*

There appears to be a lack of *in situ* short courses within existing research institutions in developing countries, although this the best way of building biotechnology capacity in the long term. As biotechnology skills and training are generic in nature and transferable, they can be applied to any commodity. There is a need to fund such courses from funds which are not necessarily project-related. The most successful outcomes from biotechnology arise from incorporating biotechnology into existing research programs in particular commodities.

#### *Recommendation 15*

*That in fulfilling its capacity-building mandate, ACIAR give consideration to funding short in situ courses in selected institutions in partner countries, which can serve as regional centres of excellence, in order to develop and integrate biotechnology capability into the existing research strengths of institutions in partner countries. Such courses should include the capability to assess the safety of work with genetically manipulated organisms.*

## 2. Introduction

THE OFFICE of Technology Assessment of the US Congress definition for biotechnology has been quoted and used in World Bank publications on biotechnology as 'any technique that uses living organisms, or substances from those organisms, to make or modify a product, to improve plants or animals, or to develop microorganisms for specific uses'.

For the purposes of this paper, this definition is too broad, as it encompasses all traditional biological research. It is more useful to think of biotechnology as a bundle of more recently developed technologies, which have allowed scientists either to achieve the same outcomes faster, or to achieve new outcomes which would have been very difficult to achieve, if at all, without the use of biotechnology. The technologies are diverse, and not necessarily more sophisticated, although, on the whole, more expensive equipment and reagents are involved. As biotechnology is a means to an end, not an end in itself, it is useful to think of biotechnology as a set of tools developed in the last 20 years.

In the World Bank publications cited, biotechnology is thought of as a continuum of technologies, ranging from long-established conventional technology through to genetic engineering. This concept is often used, particularly in official US documents, to show that biotechnology need not require special regulations since it is simply an extrapolation of past technologies. Biotechnology may include technologies which represent a continuation of traditional outcomes, but it also makes possible new combinations and duplications of genetic material which cannot be achieved by traditional means, such as making genetic combinations with genes originating from widely separated taxa, or multiple cloning of animal embryos. While biotechnology may represent a continuum, it is also a departure from what might be achieved with traditional technologies.

The range of technologies that biotechnology encompasses are described in the next chapter, and the list (see next chapter for explanations) includes:

- monoclonal antibodies, gene probes, and genetic amplification and mapping technologies;
- recombinant DNA technology, use of vectors, gene libraries, and cloning in bacteria;

- modern tissue culture techniques, embryo rescue and wide crosses;
- anther culture, clonal micropropagation, and somaclonal variation;
- agroinoculation, 'biolistics', tissue culture transformation in plants;
- embryonic stem cell technologies, multiple cloning, nuclear transplantation and transgenesis; and
- site-directed mutagenesis or recombination, 'anti-sense' technology.

The list of new technologies is growing year by year. In this paper, it will not be possible to explain all these technologies, and the interested reader is directed to recently-published biotechnology texts, or to journals in relevant disciplines.

For ACIAR, knowledge and appreciation of the scope, implications, capabilities and limitations of the technologies are important in assessing whether or not to incorporate them in particular projects. It is therefore essential for Research Program Co-ordinators (RPCs) to develop and enhance this appreciation. With regard to increasing the collective knowledge of ACIAR's scientific staff of particular biotechnologies being used in various fields, ACIAR could consider the following options:

- initiate a series of in-house technical seminars where scientists are invited to present biotechnology developments in their disciplines;
- acquire the knowledge by means of a suitable appointment;
- promote in-service refresher courses in research institutions.

While the options need not be mutually exclusive, and may be appropriate at various times depending upon the inclinations of RPCs, as a minimum, if RPCs are to embrace biotechnology in their own program areas, they would need to have a theoretical appreciation of what new methods are being developed and how the techniques can meet the objectives of their own program.

### Recommendation 1

That ACIAR invite working scientists from different disciplines to explain new developments in biotechnology in a series of in-house technical seminars.

### 3. Biotechnology Applications in ACIAR's Research Program Disciplines

#### Crop Sciences Program

RECENT developments in plant biotechnology have involved the transformation by recombinant DNA technology [1] of a range of plants. The list of crop species that can be genetically engineered has grown daily since the first tobacco and petunia plants were transformed in 1983. Wheat is the most significant crop to be transformed and this was achieved in 1992.

Transformation of dicotyledons is now routine, and is achieved by the use of the crown gall bacterium, *Agrobacterium tumefaciens*, as a vector to carry the gene of interest into a plant cell. *A. tumefaciens* transfers a portion of its large plasmid [2], Ti, into the chromosomal DNA [3] of the plant. The DNA transferred causes gall formation. It is possible simply to insert the gene of interest into the Ti plasmid, or by using a binary vector, where the foreign DNA is carried on a second plasmid, to transform tissue culture cells. Since the crown gall organism is a pathogen and causes crown gall disease, the cancer-causing genes are first eliminated from the Ti plasmid which is capable of entering the plant cell and integrating into the genome, without the gall-inducing oncogenes.

Successful transformation invariably involves the development of a tissue culture system which can regenerate the whole plant, a scoring system so that the transformed cell can be identified (usually achieved by means of an antibiotic or herbicide resistant marker) and a 'reporter' gene (such as the luciferase gene) so that the tissues expressing the introduced gene can be identified, once the transformed cell regenerates into the whole plant.

The transformation of monocotyledons has been more difficult as *A. tumefaciens* does not infect monocotyledons, but is achieved by means of 'shooting' pure DNA of the isolated gene of interest into meristems or tissue culture by means of a gene gun—'biolistics', or by injecting the vector, *A. tumefaciens*, with the gene of interest using a 'gun', a technique called 'Agroinoculation'. 'Biolistic' methods involve the acceleration of small metal particles (gold or tungsten) coated with DNA to penetrate plant cell walls.

Transformation experiments can achieve traditional plant breeding goals in a more rapid and specific way than by the use of traditional crossing experiments, and they can also achieve novel combinations of genes and new genotypes. The incorporation of

genes from other unrelated organisms, such as animals and invertebrates, is not achievable by any other technique.

Use of embryo rescue [4] and sophisticated tissue culture techniques has enabled genomes from different plant families or more distantly related plants, to be crossed—'wide crossing'. Other important uses of biotechnology are the use of DNA and RNA [5] sequences as probes for detecting the presence of particular sequences, and genetic mapping technology using restriction enzymes (which cut the DNA at specific sequences) and comparing the lengths of fragments generated on polyacrylamide gels—restriction fragment length polymorphism (RFLP).

Biotechnology has been applied to crop plants to achieve the following:

- pest resistance—BT cotton, potato with coat protein gene of potato leaf virus, peanut with peanut stripe virus coat protein gene;
- herbicide resistance—herbicide resistant cotton, lupins;
- higher yields—potato with cytokinin gene;
- elimination of toxins—canola, tomatoes;
- novel characteristics—blue colour in roses and carnations;
- reproductive isolation—male sterile canola;
- biological control of diseases—genetically engineered bacteria for control of crown gall in stone fruit, 'take-all' disease in wheat, and bacterial wilt; and
- tolerance to abiotic factors—salt, drought, cold, frost tolerant plants.

See Appendix 1 for the genetically manipulated organisms developed and trialed in Australia. Some applications, such as the alleviation of poverty, sustainable production and ensuring global food security, are more relevant to ACIAR's corporate values, than others. Pest-resistant transgenic crops lose their effectiveness once resistance in pest populations develop and should only be deployed as part of an integrated pest management strategy. Plants with herbicide resistance genes (used as a selection marker, so that herbicides can be used to kill the cells without the transgene) require the use of specific herbicides which may result in increasing input costs for the farmer, while constructs such as blue roses appeal to a very small wealthy market. Reproductive isolation may be a useful management tool under some agronomic conditions, for example to prevent outcrossing of a transgene which may be a problem when expressed in wild

relatives. However, by and large, reproductive isolation would secure for the company developing the product, a dependent market for the continued supply of seed.

ACIAR's Crop Sciences Program could support applications in priority commodity crops to increase yields, to achieve pest and disease resistance, and to achieve abiotic tolerance, and assign a low priority to applications such as herbicide resistance and to reproductive isolation. However, the value of particular applications to the objectives of the Crop Sciences Program would need to be assessed on a case-by-case basis.

### **Animal Sciences Program**

Technological developments in animal research have been so rapid, particularly in embryo manipulation technologies, that no single publication containing a description of all the available techniques appears to exist. Developments in embryo technology include the ability to freeze and to store totipotent [6] stem cells derived from early embryos, and to reimplant these into pseudo-pregnant animals [7] and again go through another round of harvesting of stem cells at the blastocyst stage. This quickly leads to the collection of many genetically-identical stem cells, and thus to multiple cloning of a single genotype on a scale not previously achievable. Replacement of the nucleus of a totipotent cell with another with a desired genotype gives this powerful technique greater flexibility.

Transgenic technology allows for the microinjection of pure DNA of a particular gene from any source into the fertilised egg or into stem cells. This generally results in random multiple-copy insertion of the construct into the genome at a low frequency. More sophisticated technology using retroviral vectors [8] with genetic material containing flanking sequences to the proposed site of insertion, will allow targeted insertion by homologous recombination [9]. Gene function can be disrupted using 'knock out' technology where a functional gene is replaced by a defective one, or by the use of 'antisense' technology [10]. Successful transgenesis and expression requires the use of suitable promoters [11] which can be triggered by external factors (e.g. metals in the diet) and a selection marker generally based on drug resistance. Research on the manipulation of sperm (which is easier to harvest and available in quantity) rather than eggs, has just begun.

Immunological developments are also proceeding apace, and a number of veterinary diagnostic kits arising from recombinant DNA technology are already on the market. Vectors for carrying antigens based on attenuated animal viruses—fowlpox for poultry disease, vaccinia, and others, are being developed as vaccines against viral and bacterial diseases. The development of vaccines against multicellular parasites is taking longer, either because it is difficult to identify the immunogenic antigens concerned, or more fundamentally, because infection does not necessarily produce immunity against superinfection. Nevertheless, there is a cattle tick vaccine on the market which does reduce the parasite burden as well as other prototype vaccines. The manipulation of the hormones and 'immunogenetics'—developing vaccines which either carry the hormone or its receptor protein—can modulate fertility, lactation and muscle enhancement.

Hence, biotechnology could be applied in all areas in the ACIAR's Animal Sciences Program:

- productivity—enhancing growth rate, earlier weaning, enhancing milk production and muscle growth;
- nutrition—transgenes for biosynthetic enzymes for the endogenous production of particular amino acids e.g. cysteine, improving nutritive value of pasture grasses, lupins etc, removing toxins from feedstuffs, gut microflora manipulation;
- health—vaccines against viral and bacterial diseases, diagnostics;
- stock—multiple cloning, increasing litter size, improving desirable characteristics and deleting undesirable genes; and
- management practices—manipulating 'oestrus', eliminating taints in meat so that animals need not be castrated.

A serious constraint in animal biotechnology is the public acceptability of the technology and of the resulting food product, and ethical concerns arising animal experimentation in general, which will be discussed later in this paper. Only one proposal for a transgenic animal, a transgenic pig with porcine growth hormone gene, has been submitted for bio-safety assessment in Australia, but no decision has yet been taken.

ACIAR's Animal Sciences Program could give priority to aspects which are relatively uncontroversial, such as the development of vaccines and increasing the nutritive value of feedstuffs, and assign low priority to animal transgenesis.

## Postharvest Technology Program

The same range of technologies described in the Crop Sciences sub-section, is applicable in the postharvest area. Biotechnology can achieve the objectives of reducing losses due to postharvest diseases and of extending shelf-life. 'Antisense' technology (DNA with the sequence of the gene in reverse orientation) has been used to block the ethylene biosynthetic pathway, or an enzyme which degrades cell walls, thus delaying ripening of fruits and vegetables. At least one such product is available in the marketplace. Tropical fruits are more prone to rapid deterioration than temperate fruits, so the problem of delaying ripening is more urgent for these products.

The incorporation of the coat protein of gene of a virus provides resistance to infection, although the mechanism for this effect is not completely understood. Another strategy which may be useful to pursue, is to delay the onset of disease symptoms in infected fruit by means of manipulating host defence mechanisms.

Postharvest applications include:

- delayed ripening of vegetables and fruits, such as the Flavr Savr tomato, now on the US market;
- biological control of post harvest diseases—stem rot control;
- fermentation characteristics—increasing the sugars which can be used as substrates, making cheese starter cultures resistant to bacteriophages;
- flavour and taste—genetically engineered sweeteners;
- processing characteristics—juice and pulp consistency, change viscosity of tomato pulp; and
- additives for nutritional characteristics—e.g. lysine or methionine biosynthetic genes added to cereals.

One of the technical difficulties is the limited number of fruit species for which tissue culture systems have been developed. Other difficulties relate to regulation, and the low customer acceptance of genetically engineered food products by some sectors of the community. These issues are dealt with in Chapter 6.

## Forestry Program

Again the same technologies described for crops can also be used in forestry. Clonal micropropagation [12] has an important role to play in the rapid multiplication of relatively rare superior genotypes, e.g. some tropical hardwoods. As with traditional technology, the major objectives in tree breeding are vigour, stem

form and wood quality. For some niche markets, genetic engineering applications, include:

- lignin reduction in pulp species;
- cold tolerance to increase range sites for species e.g. eucalypts; and
- insect or fungal resistance.

Difficulties include the long field testing period required for assessment of transgenic trees, and for back-crossing programs, because of the generation time of some species. As well, tissue culture techniques are not sufficiently advanced in a number of important industrial species for genetic manipulation to be contemplated.

A recent Food and Agriculture Organisation (FAO) paper (Haines 1994) predicts that tropical sites will be most likely to meet the predicted global demand for industrial plantations of 100 million ha, and non-industrial plantations of several 100 million ha. Biotechnology may be the most promising way of meeting these targets.

## Land and Water Resources Program

The sustainable use of land and water resources includes the use of microorganisms as biofertilisers. These fall into the following groups:

- symbiotic nitrogen-fixing bacteria, such as *Rhizobia* species;
- mycorrhiza-forming fungi;
- phosphate solubilising fungi;
- plant associated microorganisms such as endophytes, and free-living root zone microorganisms; and
- algal biofertilisers such as *Anabaena*.

Transfer of bacterial nitrogen-fixing genes into plants is some way off in the future because of the complexity of nitrogen fixing genetics. *Rhizobium* has long been the target of genetic manipulation and recombinant strains which combine good nodulating characteristics with efficient nitrogen-fixing, and are now available on the market. However, in practice, one of the difficulties is to get an efficient strain to replace endemic strains in the soil. Work underway at present enhances the competitiveness of the introduced strain. Strategies include:

- making the strain resistant to some agent that kills other *Rhizobia*;
- creating or taking advantage of the 'fit' between a specific strain and host species; and
- enhancing the likelihood of the inoculum interacting with the host (e.g. by use of flavonoids).

Other applications for soil microorganisms include biological control agents for diseases such as crown gall, and Australia was the first country to put a genetically engineered product on the market for this purpose. The possibility of using endophytes [13] as vectors for a whole range of characteristics including increasing yields, adding hormones and nutrients, is currently being explored.

The genetic manipulation of soil microorganisms usually involves using antibiotic resistant markers, as selection involves killing non-recombinant strains with the antibiotic. Most of the antibiotic resistant markers are already prevalent in soil microorganisms, but it may be necessary to ascertain at the proposal stage that the marker does not give resistance to an antibiotic commonly used in veterinary practice.

### Aquaculture Program

Biotechnology has little relevance to the harvesting of wild stocks and will not be discussed here, sustainability and management being the main issues for this type of fishing. Over-exploitation is already a significant problem globally and is rapidly leading to the depletion of marine resources particularly for developing countries which depend on marine resources for food. Aquaculture provides the best hope of sustainable production to meet increasing demand in the long term.

Biotechnology can be applied to contained aquaculture systems, but the use of such technology is in its infancy. Among the applications being developed in Australia, North America and in Europe, are:

- hypophysation—induction of spawning by injecting pituitary gland extracts into mature fishes;
- sex reversal or reproductive isolation—administration of hormones;
- formulation of feed—culture of bacteria or microalgae;
- gynogenesis (production of all female offspring), triploidy and tetraploidy—with more than the normal complement of chromosomes;
- transgenesis—growth hormone, insulin, vitellogenin, anti-freeze protein genes;
- vaccines and diagnostics—e.g. monoclonal antibodies for the detection of *Vibrio* species; and
- production of biological products from algae—beta-carotene from *Dunaliella*.

Developing countries are already using hypophysation and sex reversal. Diet formulation and diagnostics are at the development stage. However, at present, genetic

engineering is exclusively being undertaken in developed countries. Unlike the more limited response seen in mammals, transgenic fish with extra piscine growth hormone genes grow many times their usual size, provided feed is not limited. This has been demonstrated dramatically with Pacific salmon at the government agency, 'Fisheries and Ocean', Canada.

An analysis of the needs of developing countries (Guerrero 1991) identified the following applications as being appropriate for Asian aquaculture:

- genetic improvement of cultured species for improved growth, disease resistance and adaptability to new farming systems;
- development of low-cost but efficient grow-out diets for cultured fish using locally available foodstuffs and microbiological cultures;
- production of vaccines and monoclonal antibodies for the prevention and control of bacterial and viral diseases;
- development of drugs and other biotechnological products from marine organisms.

One of the problems of the genetic engineering of fish is the difficulty of maintaining strict containment conditions to prevent the escape of transgenic fish, eggs, fry and gametes. If a net is used, the mesh size should be small enough to prevent the escape of gametes and strong enough to withstand large pressures, which makes this impracticable. Contingencies such as flooding and run-off make containment a serious problem. The production of sterile fish may be a early and appropriate objective of genetic engineering.

### Agricultural and Natural Resource Economics Program

As biotechnology comprises a range of diverse tools, its impact is the same as that arising from traditional technologies. It can decrease the cost of inputs, lower production costs, and increase output for the same input costs, as well as increase the quality and value of crops. However, benefits will only arise if the technology is applied appropriately and adopted. Biotechnology can also be capital intensive, raise the cost of the final product, and can increase the cost of labour by the use of skilled personnel.

It may be useful to think of the economic impact of biotechnology in time-frames. In the short term, as laboratories are investing in equipment and scientists are being trained, the impact on costs could be significant. In the medium term, biotechnology will be used

as a substitution technology to produce the same products more efficiently, and therefore, could increase profits and returns to farmers. In the long term, it has the potential to revolutionise agricultural production systems by breaking through present productivity ceilings, e.g. reducing usage of chemical inputs, farming of marginal agroecological zones, maximising sustainability of renewable resources, use of superior genotypes in terms of yields, reduction of waste, pest and disease resistance, and tolerance to abiotic conditions. The result in the long run is the more efficient use of natural and agricultural resources.

### Options

The present ACIAR portfolio of on-going and completed projects is seen in Appendices 2 and 3 (information in these appendices as at May 1995). Biotechnology comprises a low proportion of ACIAR's 300 completed projects and over the last 12 years only 14 have used biotechnology. This low proportion is gradually increasing and a higher proportion of proposed projects plan to use biotechnology. It appears that there is no deliberate attempt by the project leaders or RPC's to promote the use of biotechnology in projects and its use is purely incidental. Decisions on methodology should be based on an assessment of the effectiveness and efficiency of the method concerned to achieve project and program objectives, within the limitations of facilities and expertise available in particular developing countries. Biotechnology may be the appropriate methodology in some projects and can enhance and complement traditional methods.

ACIAR could contemplate the following options:

- do not incorporate biotechnology into projects;
- have a separate biotechnology program;
- include biotechnology projects in all programs where it is the most effective means of meeting the project objectives.

Not using biotechnology at all is not a viable long term option, as opportunities for successful outcomes will pass ACIAR by as institutions in Australia and in ACIAR's partner countries increasingly use new technologies. Having a separate biotechnology program would deny its generic nature, and shut out its potential to contribute to the objectives of all ACIAR's programs.

It is thought, even by pessimists, that biotechnology offers the best hope of raising productivity and

meeting global demands for food in the future (Tribe 1994). It can be seen from the above analysis that biotechnology has the potential to contribute to ACIAR's program objectives. The rational option, therefore, is to incorporate biotechnology into projects in all programs. Since biotechnology provides a powerful set of tools, it can achieve objectives in all program areas.

The application of biotechnology is most likely to be successful when integrated into traditional species improvement breeding programs for the species concerned, particularly where tissue culture methods and micropropagation techniques are advanced.

### Recommendation 2

**As biotechnology provides a set of tools to achieve research objectives, it has the capacity to contribute to all program areas, and could be integrated into projects where its use is the best way to achieve the objectives of the project. It can complement traditional research methods, and is most successful when augmenting pre-existing research strengths in the partner country.**

### Endnotes on Chapter 3

1. Transfer of genetic material between organisms using a vector so that the resulting organisms carries a segment of genetic material from another organism joined to its DNA.
2. A small, extrachromosomal, circular DNA that is used to transfer genes from one organism to another.
3. Deoxyribose nucleic acid, the composition of the polymeric molecule that carries the 'blueprint' of the organism.
4. The process in plant breeding whereby tissue from young embryo plants is excised and propagated *in vitro* for subsequent growth as differentiated plants.
5. Ribonucleic acid, the chemical composition of some viruses and 'messenger' in all cells carries the genetic code from the nucleus to the cytoplasm where proteins are synthesised.
6. Undifferentiated embryonic cells with the potential to develop into the whole multicellular organism.
7. Simulating the physiological characteristics of pregnancy in animals by the use of hormones.
8. Viruses with RNA genomes which are synthesised into DNA by the cellular enzymes, once they infect a cell, and become integrated into the DNA of the cell.
9. Exchange of DNA between two genomes at points where the sequences are identical.

10. Introducing genetic material into the cell with the gene concerned in reverse orientation (so that the code is read backwards) so that normal reading of the gene synthesis of the protein is disrupted.

11. Sequences of the DNA occurring before a sequence coding for a protein which act a 'switch' to turn on expression of the gene.

12. Propagation *in vitro* from undifferentiated callus tissue of a plant to give multiple plantlets.

13. Organisms which live in the vascular tissue of higher plants.



## 4. Australia—Strengths, Weaknesses, Opportunities and Constraints

### Strengths

It is beyond the scope of this paper to describe Australia's biotechnology research strengths and weaknesses in any detail. Agricultural research, including biotechnology, has historically been strong in terms of funding, performance and outputs. Australia embraced biotechnology after the discovery of restriction endonucleases was made in the early 1970s and after then, every graduate from any Australian university in the biological sciences has been through courses which incorporate the latest techniques in biotechnology. Australian commissioned organisations in ACIAR's projects including CSIRO's agricultural divisions, universities and state agricultural institutions, have pursued and applied biotechnology in all fields of research.

More recently, the Australian Government has established Cooperative Research Centres (CRCs) to bring together CSIRO, universities, state agencies and industry to enable a 'critical mass' of research effort to be brought together, so that commercial products may be developed. The CRCs applying biotechnology (and their contact details) relevant to ACIAR's programs are listed in Appendix 4, and are a good indicator of Australia's research strengths. Although the CRCs are directly concerned with developing products for Australia rather than for developing countries, CRC managers will be able to put ACIAR Research Program Coordinators in touch with particular scientists and institutions with strengths in the areas concerned, and thus serve a useful networking function.

To complement its strong research infrastructure, Australia also has good information dissemination mechanisms and extension services to farmers to deliver the products and services arising from agricultural research.

Australia has strengths in the biosafety assessment of genetically manipulated organisms and its non-statutory monitoring system was established in 1975 with the publication of the first set of national guidelines for recombinant DNA work by the Australian Academy of Science Committee on Recombinant DNA. These guidelines preceded the US Guidelines. The monitoring system has gone through a number of incarnations and the Genetic Manipulation Advisory

Committee (GMAC) in the Commonwealth Department of Administrative Services now overviews genetic engineering in all Australian institutions.

In 1990, the Minister for Industry, Technology and Commerce submitted a reference to the House of Representatives Committee on Industry, Science and Technology to examine the issues concerning genetic engineering and the adequacy of the present advisory system. The Inquiry Report, published in 1992, recommended the establishment of a new legislative authority with an expert committee like the present GMAC, reporting to it. Although the Government accepted the thrust of the recommendations of the Inquiry, there have been difficulties in getting agreement from all the states for a national legislative system to approve releases of genetically manipulated products into the environment.

Another of Australia's strengths is the quality of its tertiary education system, which has attracted students from its regional countries especially from Southeast Asia, since the days of the Colombo Plan Scholarships. The university system was expanded in the 1980s, and some of the newer universities did not have a research tradition, consequently the quality of biotechnology courses in some universities is variable.

Australia has an industrial patent legislation which covers living organisms, and is a signatory to the Union of Convention for the Protection of New Varieties of Plants (UPOV) and the Biodiversity Convention.

### Weaknesses and Constraints

Australia's weaknesses in biotechnology tend to be the same as its weaknesses in all other research fields. These include the low proportion of private sector investment in research compared to other OECD countries, the lack of an industry sector of sufficient size to take products successfully through the development and marketing phases, through regulatory hurdles and on to the supermarket shelves, and the relatively low proportion of strategic and applied research compared to other OECD countries. These issues have been the subject of many Government reports.

Although Australia has expertise in molecular biology, and in the agronomy of its main agricultural commodity products—e.g. wheat, cotton, sugarcane, it has little experience with the cultivation of commodities which may be of interest to partner countries

such as rubber, palmoil and some tropical fruits. Consequently, Australia has much to learn as well as to teach its partner countries in collaborative research projects. This is an important factor in the successful application of biotechnology to particular species. Since biotechnology provides a set of tools, expertise in the species to be transformed as well as expertise in the use of the tools themselves, is necessary for a successful outcome.

Constitutionally, Australia is a federation of states which have responsibility for delivery of agricultural services, but the research funding system is pluralistic, comprising Commonwealth organisations like the CSIRO, State Departments which also undertake research, commodity-based Boards and Corporations, as well as strong interest groups such as the National Farmers Federation. Consequently, the nation as a whole has a diversity of funding sources and policy advisory mechanisms which together act to balance

any distortions, or tendencies to skew agricultural research in any particular direction. Unlike the centrally-directed biotechnology programs of ACIAR's partner countries, Australia's biotechnology projects are funded from a diverse range of sources, with differing priorities.

### **Opportunities**

Australia has negotiated Science and Technology Agreements with a number of developing and developed countries in the Pacific region in order to establish cooperative science and technology ventures. In the area of biotechnology, Australia's strengths is in its research capacity, scientific expertise and regulation.

In summary, Australia can offer research and policy expertise, and a variety of biotechnological tools which underpin all biotechnology research, training and biosafety assessment, to its partner countries.

## 5. Partner Countries—Strengths, Weaknesses and Constraints

### India, China and Southeast Asia

BIOTECHNOLOGY can only be successfully applied within existing research programs. In order to carry out collaborative research involving biotechnology, the partner country needs to have an existing research capacity. Of ACIAR's partner countries in its traditional geographic mandate, those which have any significant biotechnology capability are:

- China (Appendix 5);
- India;
- Indonesia (Appendix 6);
- Malaysia (Appendix 7);
- Pakistan;
- Philippines (Appendix 8);
- Thailand (Appendix 9);
- Vietnam (Appendix 10).

The region comprising the Indian Subcontinent, China and Southeast Asia is the most important region for Australia in terms Official Development Assistance (ODA) expenditure. Expenditure for Southeast Asia alone exceeded that for Papua New Guinea in the 93-94 AusAID budget for the first time, at \$365 million. Among the countries in this area, there are strengths in traditional commodity research, as listed below:

- China—rice, pigs, wheat, tobacco, maize;
- India—rice, pulses, milk, wheat, fuelwood;
- Indonesia—rice, soybean, garlic, potato, banana, timber;
- Philippines—coconut, rice, bananas, maize, fisheries;
- Malaysia—rubber, oil palm, cocoa, pepper, timber;
- Thailand—rice, cassava, ornamental flowers, tropical fruits, fisheries; and
- Vietnam—rice, maize, cassava, fruit, root and tuber crops.

ACIAR's Country Managers were asked to supply information relating to the country strengths in infrastructure and the research activities conducted in them. As well, information on programs, policies, biosafety and intellectual property rights (IPR) status was also sought. Appendices 5-10 present this information for China, Indonesia, Malaysia, the Philippines and Vietnam. Where there was no country manager, the information was derived from Sasson 1993, and Komen and Persley 1993.

### Policies, Programs and Biosafety Regulation

In general, biotechnology research programs and policies have been centrally funded and coordinated by national governments in all eight countries.

China has drawn on the extensive research capacity of the Chinese Academy of Agricultural Sciences (CAAS) by creating the Biotechnology Research Centre to focus biotechnology research in CAAS Institutes. The China National Centre for Biotechnology Development (CNCBD), created in 1983, coordinates all biotechnology research and development (R&D) activities, including training and international cooperation. The six main biotechnology research centres under the CNCBD are listed in Appendix 5.

Biotechnology, among other high-technology, was a priority area identified under the 863 Program (established in March 1986) by the State Science and Technology Commission. Research priorities, with a budget of US \$20 million, were identified as:

- varieties of plants and animals to increase yields of grain, meat, milk and fish;
- protein engineering and genetic engineering; and
- development of new drugs.

China has strengths in the area of fermentation technology and plant tissue culture. There are about 1000 research units engaged in either tissue culture or another culture work, and this has served as a springboard for the early and rapid development of genetic engineering of plants.

China has no regulatory system for biotechnology in spite of having many thousands of hectares under cultivation with transgenic crops, mainly tobacco.

India also has a centrally coordinated program in biotechnology, first established under the Sixth Five Year Plan (1980-85), with the setting up of the National Board on Biotechnology in 1982. Subsequently, the Board's functions were assigned to the Department of Biotechnology (DBT) in the Ministry of Science and Technology. Its role is to:

- develop integrated plans and programs in biotechnology;
- identify specific R&D programs in biotechnology and biotechnology-related manufacturing;
- support biotechnology infrastructure development;
- facilitate the import of biotechnological processes, products and technology;
- formulate biosafety guidelines for laboratory research and applications.

The DBT has Action Plans where priorities are established. Agricultural biotechnology research is coordinated by the Indian Council of Agricultural Research, which funds the infrastructure for agricultural research.

India has a set of Recombinant DNA Safety Guidelines for research with genetically manipulated organisms and institutional biosafety committees within centres engaged in biotechnology research. These committees are guided by the Review Committee in the DBT. As well, the Department of Environment has a Genetic Engineering Approval Committee for the review of large-scale and field release applications.

There is a national network for biotechnology research in **Indonesia** comprising of a number of institutions but the primary responsibility for implementing agricultural biotechnology programs lies with the agency for Agricultural Research and Development (AARD) and its Central Research Institute for Food Crops (CRIFC). AARD has recently been restructured so that each research institute of AARD is confined to its own mandate commodity, and has established a Research Institute for Biotechnology in Bogor. As well, there is a very well equipped Research and Development Centre for Biotechnology funded by the Indonesian Institute of Sciences (LIPI).

A number of new institutes, called Institutes for the Assessment of Agricultural Technologies (IAATs) have recently been created for downstream development and trialing of products from a Research Institute. See Appendix 6 for a comprehensive list of institutions engaged in biotechnological research (biotechnology here is interpreted very widely as any biological research).

The National Committee for Biotechnology was established to implement biotechnology policy, including guidelines for regulation of biotechnology and intellectual property rights. At present, there is an *ad hoc* committee comprising experts which is summoned by government agencies requiring advice on the biosafety of specific projects.

Three inter-university centres (IUCs) were established in 1985 financed by World Bank loans amounting to US \$23 million:

- IUC for Agricultural Biotechnology at Bogor which undertakes research in tissue culture, microbiology, molecular genetics, fermentation, *Rhizobium* and mycorrhiza inoculants;
- IUC for Industrial Biotechnology at Bandung—microbiology and fermentation, enzyme technology, waste water treatment;

- IUC for Medical Biotechnology at Gajah Mada University, Jogjakarta—vaccine production for tropical diseases.

The IUCs train faculty members from other universities, conduct post-graduate research programs and establish links with industry.

**Malaysia** has just set up (April 1995) the National Biotechnology Directorate in the Ministry of Science, Technology and the Environment with a budget of 100 million ringgit over 3 years for the National Biotechnology Program. The Directorate will take over all the functions of the National Biotechnology Working Group, which was established in 1991 to:

- advise the government on policy issues of research funding and incentives to industry;
- monitor new developments in biotechnology;
- facilitate R&D cooperation between research institutions and industry;
- establish safety and ethical guidelines.

The Directorate is also considering funding a central bioprocessing manufacturing facility. Priority investment areas of the Directorate include:

- diagnostics, vaccines and other health products;
- plant tissue culture;
- biotechnology of oleochemicals;
- natural products screening and development; and
- environmental biotechnology.

Malaysia has excellent agricultural research infrastructure, with four main commodity research institutes:

- the Malaysian Agricultural Research and Development Institute (MARDI);
- the Palm Oil Research Institute of Malaysia (PORIM);
- the Rubber Research Institute of Malaysia (RRIM); and
- the Forest Research Institute of Malaysia (FRIM).

As well as these four agricultural research centres, several plant biotechnology programs are carried out in universities, including the University of Malaysia, the National University, the Science University of Malaysia and the Agricultural University of Malaysia.

The Government of **Pakistan** has established the National Institute for Biotechnology and Genetic Engineering (NIBGE) at Faisalabad, affiliated with the Quaid-e-Azam University, Islamabad. NIBGE has six research groups:

- plant biotechnology—plant genetic engineering for crop improvement;
- biofertilisers—genetic engineering of microorganisms such as *Frankia* and *Rhizobium*;

- **biofuels**—microbial conversion of biomass to alcohol and methane gas;
- mineral and fossil fuel biotechnology—microbial liquefaction of high grade fuels;
- environmental biotechnology—includes bioremediation and biosafety assessment of the environmental release of genetically engineered microorganisms; and
- basic biology—monoclonal antibodies and vaccine production.

NIBGE has international linkages with research groups in the US and Europe.

The Science and Technology Council of the Philippines, through its Sectoral Technical Panel on biotechnology identified the following priorities for 1991–95:

- coconut tissue culture;
- production of high-value fats from coconut oil;
- human, animal, and plant diagnostics and vaccines;
- reforestation through tissue culture;
- penicillin production using locally available raw materials; and
- treatment of human waste.

The Philippines also has a central national biotechnology institute—the National Institute of Biotechnology and Applied Microbiology (BIOTECH) founded in 1979 to:

- provide direction and support for biotechnology research;
- provide training to support industry;
- provide scientific advice to Government; and
- facilitate commercial applications of biotechnology.

Stringent biosafety guidelines for case-by-case assessments have been drawn up by the National Committee on Biosafety (NBC) established in 1990, and the Philippines has a system of institutional biosafety committees. The NBC coordinates other agencies involved with regulations such as quarantine services.

A central national agency in Thailand, the National Centre for Genetic Engineering and Biotechnology (NCGEB) was established in 1983 to coordinate biotechnology activities and supports research in five laboratories at the universities of Chulalongkorn, Mahidol, Kasetsart, Chiang Mai and the King Mongkut Institute of Technology. These centre focus on work in:

- tissue culture;
- plant selection and germplasm conservation;

- biofertilisers;
- pest control; and
- rice.

A new Bioservice Unit has been established by the NCGEB at Mahidol University, as a core facility for the common use of expensive instruments such as DNA synthesisers. In 1991, the NCGEB was brought under the National Science and Technology Development Agency.

Thailand has guidelines on biosafety drafted by the Biosafety Subcommittee of the National Committee for Science and Technology.

After much preparation, the Vietnam Government in 1994 released a National Strategy Directive for Biotechnology Development. The two goals of the strategy were:

- the establishment of research facilities, including the foundation of the Institute of Biotechnology in the Centre for National Science and Technology, and laboratories at universities—see Appendix 10 for a complete list; and
- the establishment of the National Biotechnology Program under the National Council for Biotechnology—see Appendix 10 for priorities of the program.

Funding for the projects undertaken in the facilities is largely from US official development aid.

#### Weaknesses and Constraints

The following constraints were identified in various papers at a recent International Service for National Agricultural Research (ISNAR) Conference titled 'Turning Priorities into Feasible Programs'—a regional seminar on planning priorities and policies for agricultural biotechnology, 25–29 September, 1994:

- human resource constraints including lack of technical knowledge and research experience;
- uncertain or inadequate proprietary protection for biotechnology (See Appendices 5–10);
- lack of awareness of biosafety assessment procedures, or inappropriate regulations;
- inadequate communications and extension networks to disseminate results;
- weak science base at tertiary institutions; and
- the lack of infrastructure and capital investment.

All the developing countries are either actively examining proprietary protection for biotechnology, or are making the protection of plants, animals and microorganisms explicit in existing IPR legislation, particularly industrial patent legislation, *post* the

Uruguay GATT round. At the present time, the status of IPR protection for biotechnology is unclear in most developing countries, with the exception of China and Thailand where biotechnology is protected under recently amended patent legislation. Even in the case of China, plant and animal varieties are not explicitly covered.

Some of these constraints can only be addressed by the government of the developing country concerned, using IPR legislation, but developed countries can play a role in overcoming others. The subsequent sections of this paper deal with ACIAR's role in overcoming constraints relating to IPR, biosafety, training and capacity building.

### **Other regions**

Countries of the other regions in ACIAR's geographic mandate (Latin America, the Pacific and Africa) do not have any significant biotechnology research capacity, and still require assistance in setting up facilities and training personnel for traditional research in specific commodities.

Some African countries such as Zimbabwe, Kenya and Tanzania are developing a biotechnology

capability, as are some countries in Latin America. However, the presence of other donors in these regions (European countries in Africa and the US in South America) makes it less important for Australia's Official Development Assistance (ODA) and this is reflected in Australia's ODA expenditure for these regions. Countries of the sub-Saharan region, in addition, suffer from political instability, the lack of any infrastructure (e.g. communications, extension and distribution networks) and serious degradation of all natural resources. These countries would not, in general, be suitable partners for biotechnology collaboration (except where collaboration involves an international agricultural research centre, IARC).

Some IARCs are located in these regions and are dealt with separately in Chapter 7 of this report. In general IARCs are well resourced and have access to the latest technology and expertise from the international scientific agricultural community. They can thus serve as catalysts and facilitate biotechnology research in the country in which they are located. They can also provide expert technical and policy advice to country governments on issues such as the biosafety of particular projects.

## 6. Bilateral Policy Issues

This chapter deals with issues arising from the use of biotechnology in ACIAR's bilateral programs. Although these issues are associated with biotechnology, they are not confined to it, and can arise from other kinds of research. Nevertheless, biotechnology accentuates them. To address these issues, appropriate internal ACIAR policies and procedures which may need to be addressed, are identified.

Issues associated with the application of biotechnology in bilateral programs include the assessment of the feasibility-of-concept of a proposed project, the equitable and appropriate distribution of intellectual property rights and biosafety.

### In-house review

During the development of new project proposals, ACIAR projects go through in-house review at each of the first three phases of project development. Comments are sought from all scientific and economic staff at each stage, before the project can develop further to the next stage. At the Phase 1 stage, the idea for the project is first mooted and documentation is brief. The comments for this phase, include comments on the feasibility of the concept, but at present ACIAR has limited expertise to comment in detail about biotechnology projects. At Phase 2, more detailed documentation is presented against a pro-forma, and comments are also sought from external referees. At the third phase (Phase 3), documentation on the project is greater with all comments including those of in-house review, the external referees and ACIAR's Board of Management, having been addressed. The last phase (Phase 4) is the signing off stage at which the project has the necessary authorisation to commence, except for the signing of the Memorandum of Understanding with the country concerned.

ACIAR's options are:

- to leave the assessment on the feasibility and on biotechnology issues to external reviewers at the Phase 2 or 3 stage;
- to acquire, develop or contract sufficient expertise to be able to assess feasibility of concept at the Phase 1 stage.

In the interests of efficiency and effectiveness, it is desirable to make assessments at the Phase 1 stage, so that projects which have little likelihood of success are weeded out early, before reaching Phase 2 where more documentation is needed. This will save work for the project leader and for ACIAR in the long run.

It is also important to seek advice on biotechnology issues such as biosafety and the capabilities of particular partner country institutes. As an alternative to having such expertise in-house, ACIAR could have a short-list of 'consultant reviewers' paid an honorarium if necessary, where RPCs require advice at the Phase I stage. This represents the most cost-effective way to import the most current biotechnology skills when needed.

### Recommendation 3

**That ACIAR consider acquiring, developing or contracting sufficient expertise to assess the feasibility-of-concept in biotechnology projects, and to advise on issues such as biosafety and the relative capabilities of particular institutes to carry out biotechnology projects at the in-house review process.**

### Commercialisation Issues

The use of biotechnology in agricultural research is more likely to lead to the development of a novel product, i.e. new probes, useful DNA sequences, genetically engineered vaccines, novel germplasm (i.e. resistant to pests) novel biological control agents, than the use of conventional methods. Such research is likely to result in a benefit that can accrue to the private sector rather than, or in conjunction with being a 'public good'. Research using biotechnology may be subject to patents and may require intellectual property management more than traditional biological technologies. This accentuates the debate about the extent to which the public sector should be involved in funding biotechnology, for example, the public/private good dichotomy.

It was seen in Chapter 4 that one of Australia's weaknesses is the relative reluctance of the private sector to invest in research. For a variety of reasons, including the long lead time, uncertainty of outcome (high risk), uncertainty about the regulatory climate, lack of confidence in public perceptions on genetic engineering, the private sector in Australia is unwilling to invest in pre-competitive research biotechnology. Unless the overall investment climate, including government policies, changes significantly, there is a role for public sector investment in such research. However, at a certain point in the development of a product, after the basic research stage, the private sector may find investment attractive, particularly if benefits can be accrued from research which is

largely publicly funded. In Australia, as elsewhere, there is a tendency to 'privatise' public research and development. Private investment in agricultural research seldom occurs in the absence of an effective public research system.

There is a view that if investment in biotechnology is completely left to market forces (without policy intervention), the private sector might invest in high value products, such as, high yielding animal species, horticultural crops, (e.g. blue roses), while cereal and food crops might become 'orphan' crops.

As with traditional agricultural research, biotechnology may also lead to a purely 'public good' outcome, with a benefit that cannot be appropriated by the private sector. As has been the case traditionally, it is the role of ACIAR to continue to fund such research.

In view of these considerations, ACIAR has the following options:

- continue to fund only pure 'public good' research;
- fund projects only where there is little likelihood of a product developing (pure basic research);
- fund projects in the pre-competitive stage, so that companies can pick up from where public funding left off and 'privatise' the research;
- fund projects in the pre-competitive stage together with the private sector on a formula basis;
- only fund work at the product development stage.

The first option is the *status quo*, and ACIAR needs to continue to support this important category of research. Without public support, there is a grave danger that this sort of research will be neglected. However with biotechnology, funding only this sort of research may limit the attainment of program objectives by excluding research leading to patentable outcomes.

The second option is not tenable in a climate where projects are assessed *ex ante* and *ex post* for economic benefits and is against ACIAR's mandate, although it can be argued that capacity building is an important benefit which will allow the development of other products in the future. The second option is viable but not necessarily in the interests of ACIAR's partners because ACIAR will have little influence on how the IPR might be apportioned. The result might be that the developing country does not get access to the technology at a reasonable price. By the same token, Australia may not benefit if a company in the developing country commercialises the product. The last option goes against conventional economic

wisdom on the role of public investment, and will completely 'crowd out' the private sector.

If ACIAR were to fund projects on a formula basis together with industry funding, the research would not be wasted, but would result in an economic benefit which can be distributed on terms acceptable to ACIAR and in accordance with ACIAR's mandate as an international agricultural research agency. The participation of the private sector ensures further development and commercialisation of the research. Further, it is difficult for any public research agency to market products commercially off-shore, neither is a public institution best placed to enter into joint ventures with multinational companies.

In order that the maximum economic benefits accrue to Australia, it is suggested for any ACIAR funded biotechnology projects, that an Australian research and development company able to market products overseas, be associated with the project. This company will be given IPR in partnership with the partner country, in accordance with ACIAR's present policy of equitable distribution of such rights. In order to secure the commercial interests of that company, it is proposed that the company fund a proportion of the research (i.e. dollar-for-dollar or some other formula).

#### **Recommendation 4**

**If there is potential for a marketable product to be developed from the research, where feasible, an Australian company capable of marketing the product overseas could be associated with the project from its inception, and efforts be made to secure appropriate proportional (or matching) funding from the company.**

#### **Intellectual Property Rights**

Research using biotechnology is more likely than conventional research to lead to patentable outcomes and it may be appropriate to review ACIAR's policy on IPR in this regard. The 'Standard Conditions Relating to ACIAR Project Agreement' contains the following clause relating to the ownership of intellectual property:

*The ownership of all intellectual property rights protected or derived or arising solely from the performance of the services be the subject of a separate agreement entered into between the Commissioned Organisation and the Collaborating Institution, and shall be apportioned on the basis of the equitable criteria...unless otherwise agreed in writing by the parties and ACIAR.*



The philosophy of equitable sharing of rights is appropriate for an agency disbursing public funds to assist developing countries under the aid budget and is compatible with that of other international research organisations. The document also states: *all intellectual property rights ...shall vest in the Commissioned Organisation if they are rights protected in Australia, and shall vest in the Collaborating Institution if they are rights protected in the country of the Collaborating Institution.*

Developed countries are at present either extending patent laws (which traditionally cover industrial applications, and which provide stronger protection than other forms of traditional plant variety protection) to biotechnology, or have laws which already allow for the protection of biotechnology products. It is beyond the scope of this paper to discuss other forms of non-legislative protection.

On the other hand, few developing countries have such patent coverage, and in general, as users rather than developers of the technology, it is in their interests to have little or no patent protection. See Appendices 5 *et seq* for the intellectual property status of partner countries with a biotechnology capability. Difficulties in accruing rights protected by legislation arise for a number of partner countries which do not have patent protection for biotechnology. At best, protection of biotechnology is ambiguous until tested in countries including Malaysia, Vietnam and Indonesia. Signatories to the Uruguay Round of GATT are expected to define explicitly some form of legal protection for microorganisms and plants, and consequently, developing countries are now considering the explicit inclusion of biotechnology in IPR legislation, where it may otherwise be implied or excluded.

What this means is that there is little incentive for an agency to come up with a patentable product, which might be freely disseminated in a developing country, and thus undermine any existing patent protection in Australia. Under these circumstances, ACIAR's role would be to specify the terms on which the partner country has access to the technology, either through compulsory licensing or other contractual arrangements, which could include strict instructions to prevent further dissemination of the technology. It is particularly important to ensure that the developing country receives access to the technology on more favourable terms than any other country, particularly if the germplasm which led to the development of the product originated in the country

concerned (See also discussion on biodiversity in Chapter 7).

As was seen in the previous section, the use of biotechnology is more likely to lead to a patentable product than conventional agricultural research. In ACIAR's project development procedures, it is important to seek a statement of intent relating to IPR from the commissioned organisation in the Phase 2 pro-forma document, in order to have no ambiguity about the apportioning of IPR. It should also be noted that industrial ownership is more secure if reproductive isolation is genetically engineered into the product along with the characteristic of interest.

ACIAR has the following options:

- ignore the IPR issue in project pro-formas;
- seek a clear statement from the Commissioned Organisation from the outset, and ensure access by the developing country on equitable terms.

The first option may result in the possibility of ACIAR's expenditure on the project being wasted due to the private sector subsequently capturing the benefits of the research. Thus the benefits may not be realised for the partner country.

#### **Recommendation 5**

**That ACIAR's policy of the equitable allocation of intellectual property rights is appropriate for biotechnology, and that the Phase 2 proforma be amended to seek a statement on the allocation of IPR from the commissioned organisation at that stage of project development. ACIAR could examine the mechanism of compulsory licensing arrangements for spillover benefits to other developing countries which might otherwise find it difficult to access the product.**

The patenting of animals and genetic sequences is considered to raise ethical issues, and is the subject of much international debate. ACIAR needs to adopt a cautionary stance with regard to projects where the such patenting is contemplated.

#### **Biosafety**

The release of genetically engineered live plants, animals, or microorganisms (GMOs) is associated with an uncertain degree of risk that the construct may have undesirable effects on the environment (e.g. a weed or pollutant) and in the case of crops and edible plant products and biopesticides, or biological control agents, risk toxicity to humans when consumed. Put into overall perspective, of some 1000 releases of

transgenic plants around the world, no actual hazard has yet been identified. However, appropriate biosafety assessment of all genetically manipulated organisms and field testing with monitoring is essential to allay concerns and to establish safety. There is also a perception in some quarters that the developed countries could be 'dumping' unsafe products on developing countries unfamiliar with the technology. The unapproved release of GMOs in developing countries could well reflect adversely on ACIAR's international reputation.

As seen in Chapter 4, Australia has a good regulatory system and one of its strengths is expertise in the area of biosafety assessment for the release of genetically manipulated organisms. GMAC has assessed some 45 release proposals to date, of which about 33 are plant constructs and the rest, microorganisms. A complete list of GMAC approvals is attached in Appendix 1.

Assessment is generally more rapid if the construct is made using a disarmed vector (with pathogenic genes deleted) in a host organism for which there is a deal of familiarity, and if the inserted gene has these characteristics:

- is not derived from microorganisms able to cause disease in humans, animals or plants;
- does not code for a toxin for vertebrates;
- does not comprise a replication-competent fragment of a virus or a whole viral genome, or a fragment of a viral genome that can be made competent by a host factor.

The genetic constructs as described above are exempt from the small scale guidelines, but require a planned release assessment if release is being contemplated.

The National Food Authority has adopted the OECD concept of 'substantial equivalence' for the approval of genetically manipulated organisms to be marketed as food. The food will attract no additional labelling requirements in Australia if these criteria are met:

- no substance is introduced into the diet at a level for which there is no prior established history of use;
- no substances are present which may be ethically offensive to defined group of consumers;
- no special processing is required compared to its conventional counterpart; and
- when prepared for consumption, it does not contain any substances, not normally present in the conventional counterpart, which are known to be harmful to particular individuals.

- nutritional qualities are not diminished compared to a traditional counterpart.

When a genetic manipulation is proposed in a project, it may be necessary for RPCs to review these criteria in order to ensure that the construct is likely to be safe and meet regulatory hurdles without much difficulty. Any other option may lead to delays or difficulties in getting approval for release in Australia at the end of the project. RPCs may also use the services of external 'Consultant Reviewers' to advise on these aspects.

### **Recommendation 6**

**ACIAR's Research Program Coordinators should be aware of the criteria for biosafety and food safety assessment at the genetic construct stage if a genetically manipulated organism is contemplated in the proposal.**

ACIAR's partner countries are just beginning to set up biosafety regulatory mechanisms, but there is little experience and confidence in this area. See Appendices 5 *et seq* for details. The Philippines has inappropriately stringent regulation which is stifling biotechnology research in that country. An ISNAR publication (Persley et al. 1993) has suggested that all nations set up biosafety committees. The IARCs are either setting up, or have already established in-house biosafety committees, as recommended by ISNAR.

It is suggested that for all proposed ACIAR projects involving the production and release of a genetically manipulated organism, the Australian Commissioned Organisation begin dialogue with GMAC at the Phase 2 stage (and certainly before the signing-off stage) about safety considerations of the proposal. ACIAR's responsibility is to ensure that the Australian project leader is made aware of his/her responsibilities in terms of seeking GMAC advice, so the proforma at Phase 2 should include a question asking if this project falls under the GMAC guidelines, and if so, an undertaking from the project leader that GMAC assessment and advice will be sought.

As well, the 'Standard Conditions' document or Memorandum of Understanding could be amended to state explicitly that the responsibility for getting approval from appropriate national authorities to release genetically engineered organisms, lies with the agency in the developing country. Where such regulatory mechanisms do not exist, advice should be sought from an IARC, if there is one located in the country. If not, ACIAR should assist the agency itself

to conduct a formal in-house biosafety review. Where possible ACIAR could try to ensure that Australian regulatory and assessment procedures are adhered to as a minimum standard. Any advice from GMAC on monitoring requirements should be set out in the protocol for the field trials and the results be included in the project reports to ACIAR (i.e. the project annual reports).

The option of not undertaking the above procedures would leave ACIAR and the Australian Government vulnerable to the claim made by some non-government organisations that developing countries are being used as a testing ground for genetically modified organisms, so as to avoid the stringent regulations prevailing in the industrialised countries. ACIAR, as an Australian Government agency has a duty of care to ensure that regulatory systems set by another Government agency are not inadvertently bypassed.

#### **Recommendation 7**

**The project pro-forma at the Phase 2 stage of project development should require explicitly, that the Australian project leader take responsibility for obtaining any necessary approvals, including ethical approval for animal experimentation from institutional ethics committees within the Australian commissioned organisation, and for any clearances for genetic manipulation work falling under the guidelines of the Genetic Manipulation Advisory Committee (GMAC).**

#### **Recommendation 8**

**If the field trialing of a genetically manipulated organism (GMO) in a partner country is proposed in a project, ACIAR should formally advise the relevant Ministry in the partner country of the fact prior to the release of the GMO so that any necessary clearances can be obtained. This notification can be undertaken with the contractual documentation for the project or subsequently, if the release was not foreseen at the inception of the project. Where feasible, GMAC advice on the monitoring requirements of the trial should be sent to the Project Leader in the partner country.**

#### **Recommendation 9**

**Where it is clear that the partner country has no regulatory or advisory system for the assessment of the environmental release of genetically manipulated organisms, the advice of the in-house biosafety committee of the relevant international agricultural research centre could be sought, if such a centre exists in that country. If not, ACIAR may need to assume the responsibility for commissioning such assessment in the partner country.**

#### **Project Criteria**

ACIAR's project criteria are as follows:

- Approaches to ACIAR should be made formally through agreed developing country national research organisations, and have their endorsement.
  - ACIAR should respond to research priorities established by potential partner countries with the 'push' coming from the developing country. ACIAR makes these countries aware of Australian research capabilities and its capacity to respond, and indicates whether the proposed project falls within ACIAR's own priorities.
  - Research priorities should be planned jointly so that there is a partnership from the beginning. The plans must be explicit, stating what will be done by both sides, and provide a timetable of proposed activities.
  - Where possible ACIAR support should capitalise on existing strengths in Australia, and also in the developing country, to ensure that the commitment is real and that support will enhance the prospects for successful research. Some assurance that the activity is sustainable and will continue after ACIAR support ceases, is also sought. Research supported by ACIAR must focus on soluble problems that will give results having a wide application in developing countries, and bring mutual economic and scientific benefits both to developing country partners and to Australia.
- These general criteria are also relevant for biotechnology projects. Any other option would minimise the chances for success.

## 7. Multilateral Policy Issues

### Biodiversity and Sustainability

It is likely that many of the future superior agricultural products will be developed by the use of biotechnology. Continued improvement depends upon the availability of new unimproved germplasm with characteristics not previously assessed, which can be subsequently modified for use in modern agricultural systems. Most sources of unimproved germplasm for crops of agricultural significance and their centres of biodiversity lie in developing countries, and future access to germplasm will be governed by the terms of the Biodiversity Convention. Developing countries may seek access to germplasm improved by biotechnology in return for access to their biodiversity. The Convention is thus intricately linked to biotechnology. Biotechnology has an important role to play in sustainability, because applications can lead to greater yields with current inputs, with present land under cultivation, and thus are more environmentally friendly. Biotechnology can also lead to greater sustainability of land and resource use (e.g. transgenic pest-resistant crops).

The Convention on Biological Diversity signed by 150 countries, including Australia, at the United Nations Conference of Environment and Development at Rio de Janeiro in 1992, seeks to make the conservation of biodiversity and sustainable use of genetic resources a global responsibility for the first time. This Convention, which is legally binding, came into force in December 1993. It was ratified by Australia in 1993 and by India, China, and all the countries with a biotechnology capability in the Southeast Asian region. See Appendix 12 for a full list of mandate countries with current ACIAR projects, which have signed and ratified the Convention.

Other conventions and treaties which have some relevance to the conservation of biological resources, to which Australia is a signatory, are:

- Convention on the Conservation of Nature in the South Pacific, 1976 (known as the Apia Convention);
- Convention for the Protection of Natural Resources and the Environment of the South Pacific, 1986;
- The World Heritage Convention;
- The Convention on Wetlands of International Importance Especially as a Waterfowl Habitat (RAMSAR Convention);

- The Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES);
- Agreement on Trade and Related Aspects of Intellectual Property Rights, including trade in Counterfeit Goods (Annex 1c of the GATT Uruguay Round);
- The United Nations Law of the Sea Convention.

There are further Conventions and treaties relating to the rights of indigenous peoples. These other instruments are not legally binding and it is beyond the scope of this paper to consider Australia's obligations under them.

Under the Biodiversity Convention, countries are given sovereignty to their own genetic resources in return for a commitment to adopting policies on conservation. The Convention requires Parties to consider the need for international protocols for biosafety. Access to genetic resources is subject to informed consent and should be on fair and equitable terms. Indigenous people's right to consultation and compensation, is also raised in the Convention.

It can be seen from Appendix 12 that all the countries which have a biotechnology capability have signed the Convention and are currently considering safeguarding access to their biodiversity so that scientists from developed countries cannot go 'bio-prospecting' in their forests in the future. This means that costs or conditions may be attached to the access and use of germplasm originating from these countries in the future. An important condition may be access to biotechnology from developed countries. Article 16.2 states that *access and transfer of technology to developing countries shall be provided and/or facilitated under fair and most favourable terms, including under concessional and preferential terms where mutually agreed...*

Another important document, which has been signed by 107 countries, is the FAO International Undertaking on Plant Genetic Resources, which safeguards the principle of free exchange of genetic resources for scientific purposes. The rights of farmers to have access to the benefits arising from improved germplasm, is protected in this document. Genetic resources are recognised as a common heritage to be available for use by present and future generations of all countries. The FAO is currently considering amending the document to make it compatible with the Biodiversity Convention.

While the Undertaking is being revised, it may be important for Australia to adhere to the voluntary International Code of Conduct for Plant Germplasm Collecting and Transfer adopted by the FAO in November 1993, which provides guidelines requesting collectors to seek permits from national governments, and sets out minimum responsibilities for collectors, sponsors and users of the collected germplasm. Although this will add to the paperwork, approval from partner countries should be sought in projects where it is envisaged that germplasm would be collected. The option of not having formal permission may lead to disputes subsequently relating to ownership of the germplasm under the terms of the Convention, and of any improved germplasm arising from it.

#### **Recommendation 10**

**Where it is envisaged that germplasm is to be collected in a project, the Memorandum of Understanding (MOU) for the project should foreshadow this, and seek approval from the national government under mutually acceptable terms.**

Australia was represented at the first Conference of the Parties (COP1) where the need for a protocol was raised, and at COP2 in November 1995, Australia will need to have a position on whether it supports the establishment of a protocol on biosafety. For the purpose of considering these issues, an interdepartmental committee has been established, chaired by the Department of Foreign Affairs and Trade. As well, subsequent to Australia signing the Convention, the Coordinating Committee on Science and Technology of the Office of the Chief Scientist, established a working party to examine what action, if any, needed to be taken domestically to protect access to Australia's genetic resources and to obtain a fair and equitable benefit from their exploitation. It was recognised in the ensuing report that there are currently no mechanisms for addressing these issues and an interdepartmental committee has been established to consider these matters.

Australia relies on imported exotic genetic resources for its major food crops and for agriculture and some initiatives have been taken to safeguard access to these, such as the establishment of a national network of genetic resource centres to conserve germplasm of strategic and economic importance, and to link the Australian network with that proposed by

the FAO. In contrast, Australia has a rich store of endemic forest tree germplasm and can and does benefit from export of tree seeds.

It has been argued in 'Environment and Agriculture' (Winrock International Institute for Agricultural Development, 1994), that development agencies need to take a major role in the debate on genetic conservation and biodiversity. This argument is based on the fact that development agencies have a duty to safeguard major crops relied upon by all of humanity for food. The sources of diversity from which future improvements of this germplasm can arise lie in developing countries. However, developing countries have immediate pressures to meet existing food shortages and may erode this diversity by alternative use of the land which supports biodiversity. Development agencies are in a position to fund both *ex situ* and *in situ* conservation projects and thus be the custodians of food crop varieties needed for meeting the demands of increasing global populations and of future generations.

ACIAR, whose mandate is funding agricultural research, particularly needs to be involved both at the domestic and international levels, for these reasons:

- eighty per cent of genetic diversity is found in developing countries which are ACIAR's partners;
- ACIAR activities will be directly affected by the existence of any protocol, and the free exchange of germplasm for scientific research could be jeopardised;
- the international agricultural research community can provide the funds which developing countries require for research associated with the conservation of biodiversity;
- ACIAR has expert scientific knowledge on plant genetic resources and their sustainable use; and
- ACIAR has both the technical and the financial resources to meet Australia's obligation to assist conservation in developing countries.

Since biodiversity is a global responsibility, any ACIAR initiatives should be coordinated and integrated with other international efforts, and cannot be successfully undertaken on a bilateral basis. Thus ACIAR needs to be involved at relevant multilateral fora. It is also essential for ACIAR to be represented on any domestic interdepartmental committees established under Australia's obligations from the Convention, and for ACIAR to be part of the Australian delegation to any expert meetings arising from the

Convention. ACIAR needs to formalise liaison with the Commonwealth Department of Foreign Affairs and Trade so that it is invited to participate in policy which may impact on its activities.

Any other option would leave ACIAR in a position of having its activities affected without being in a position to influence outcomes. These activities can only be successfully undertaken on a multi-lateral basis, and are discussed in the subsequent sections.

#### **Recommendation 11**

**That liaison with the Commonwealth Department of Foreign Affairs and Trade be strengthened so that ACIAR is represented on relevant Australian Government inter-departmental committees set up to consider Australia's obligations under the Biodiversity Convention, and on any international expert meetings related to the Convention.**

#### **International Agricultural Research Centres**

The network of International Agricultural Research Centres (IARCs) is supported by the Consultative Group on International Agricultural Research (CGIAR), which provides funds and technical and policy advice to the Centres. ACIAR is now (since its 'sunset' review) responsible for Australian funding for the IARCs, and is a donor and member of the CGIAR. The CGIAR accords high priority to the conservation of *ex situ* plant genetic resources, and one of its institutions, International Board for Plant Genetic Resources, is entirely dedicated to stimulating work on conservation, while the other centres concentrate on their mandate commodities. The trusteeship of all germplasm held by the Centres has been transferred to the FAO to be held for the use of present and future generations for all countries of the world without cost. Currently, IARC collections do not include animals, microorganisms, ornamental plants, or trees for timber.

As seen in the preceding section, the Convention on Biological Diversity (CBD) requires signatories to undertake *in situ* conservation activities, and it is unlikely that developing countries will devote resources to this activity when more immediate goals such as food self-sufficiency are not met. The Convention specifically states that developed countries 'shall provide new and additional financial resources' (Article 20.2) to enable developing country Parties to meet their obligations under the convention. In allocating its funding to the IARCs, ACIAR could

give consideration to funding specific research projects involved with the *in situ* conservation of genetic diversity, in addition to its funding of specific centres involved in *ex situ* germplasm conservation, and thus meet Australia's obligations under the Convention.

#### **Recommendation 12**

**That in allocating funds to the International Agricultural Research Centres (IARCs), ACIAR give consideration to funding projects in developing countries involving research associated with the conservation of germplasm, including *in situ* conservation, so that the international research community may be more likely to be granted continued access to endemic germplasm.**

The IARCs are now embracing biotechnology and are investigating the associated policy issues arising from this technology. The international activities in biotechnology are summarised in Appendix 11. To avoid duplication of effort, to strengthen linkages, and to ensure efficient use of human resources and expertise, it is important that any bilateral project which is related to an existing or proposed IARC project, should be coordinated with the IARC program. No identical project should be funded from ACIAR bilateral funds, and for related new projects, the Australian commissioned organisation should be asked to collaborate with the IARC in order to ensure that there is a value-adding component to Australian involvement.

#### **Recommendation 13**

**That ACIAR be aware of the programs of the IARCs and of new projects, including biotechnology projects, so that there is no duplication of research effort, but a complementarity is achieved to add value to the work of IARCs.**

Biotechnology depends upon the availability of germplasm resources as its starting material and converts it into improved germplasm, which may attract patent protection. Unfortunately the Convention on Biological Diversity has little to say about access to improved germplasm except that developing countries should have access '*under fair and most favourable terms*' (Article 16.10), and in the case of germplasm subject to patents '*on terms which recognise and are consistent with the adequate and*

*effective protection of IPR'* (Article 16.2). Present CGIAR policy states that Centres can consider taking out proprietary protection of improved germplasm on a case-by-case basis, and each Centre is free to devise its own policies in this regard.

Recently, a review of genetic resources within the CGIAR Centres, recommended that genetic resources in the centres be integrated and funded as single program so that policies can be developed and coordinated for the Centres as a whole.

#### **ISAAA**

The International Service for the Acquisition of Agri-biotechnology Applications (ISAAA), founded in 1991 is a non-profit organisation whose role is to transfer and apply proprietary biotechnology products to developing countries. It has successfully demonstrated the feasibility of transferring such technology, by means of a model project involving the donation from Monsanto of a potato construct with the Alpha viral coat protein genes, to a Mexican research institution.

ACIAR's role and relationship to other multinational bodies with regard to training and capacity building is discussed in Chapter 8.

## 8. Training and Capacity Building

### Role of Other Donors and Multilateral Agencies

THE role of other international institutions with a biotechnology training mandate in the Asian and Southeast Asian region, is summarised as follows:

- International Service for National Agricultural Research (ISNAR), has an Intermediary Biotechnology Service which runs seminars, workshops and disseminates publications on issues in biotechnology.
- International Centre for Genetic Engineering and Biotechnology (ICGEB) located at Delhi and Trieste offer long term training fellowships to undertake research at the two locations and short term training courses on specific scientific research topics such as biosafety assessment.
- International Service for the Acquisition of Agri-biotechnology Applications (ISAAA) has funded regional workshops on biosafety.
- Biotechnology Advisory Council (BAC), a non-profit private organisation, offers services including assessment of safety of particular projects and has held biosafety workshops in developing countries including Africa.
- The IARCs can also play a training role for scientists in the country in which they are located, and Australian core funding to IARCs could include a training quantum.

A summary of the activities undertaken by these bodies is contained in Appendix 11. In general (except for the ICGEB), these organisations offer advice on policy and management issues in biotechnology. These courses take researchers out of their own research environments for training elsewhere, often in another developing country. ACIAR should not duplicate the work of these agencies but try to complement their activities. It would not be appropriate for ACIAR to hold theoretical seminars and workshops in aspects of biotechnology in developing countries but ACIAR could consider funding Australian experts to resource these seminars, or ear-mark funds to the Crawford Fund (see below) for this purpose. This would be a cost-effective way to meet training needs for specific objectives such as management of projects, biosafety or other biotechnology policy issues.

ACIAR's options are:

- to conduct policy advisory courses in biotechnology;

- to capitalise on such courses already being conducted by other donors.

The first option would duplicate courses already being conducted in ACIAR's geographic mandate regions. It is more cost-effective to add value to these courses. Although funding should be sought in the first instance from the donor concerned, ACIAR could consider funding resource people in situations where there is a clear advantage for ACIAR to do so, for example, when the particular courses concerned meet ACIAR's training objectives.

### Recommendation 14

**That ACIAR consider funding Australian experts as resource persons in biotechnology training programs and courses organised by other donors in the region when they meet ACIAR's training objectives.**

### Building Research Capacity

It was seen in Chapter 5 that one of the input costs of biotechnology for developing countries is the high human capital, since expertise and knowledge is required for the application of biotechnologies. It was also seen that biotechnology is likely to be most effective when integrated into existing research in countries which already have a research capacity in the commodities of interest.

Developing countries are already beginning to incorporate genetic and molecular biological techniques into their on-going research programs. In order to be able to build on existing research in commodities of interest to our partner countries, which are either already using biotechnology or are intending to use biotechnology in the near future, and for Australia to capitalise on the research strengths in particular commodities of developing countries, it is important to train partner country scientists in their own research environments.

One of Australia's strengths is in the provision of molecular tools and skills in biotechnology. The most effective way of building research capacity is for Australian scientists with relevant expertise to conduct in-house short courses, seminars and workshops in the institutes of the partner country. Although ICGEB runs short technical courses, all these courses take individuals out of their research environments and train them at centres where the tools and skills that they acquire might not be relevant to their own agricultural problems.



In-house training relates biotechnology skills to relevant problems and enables a larger number of people to be trained in one institute resulting in a genuine increase in research capacity. This leads to synergy and to greater use and subsequent long-term retention of skills. What might be forgotten by a single individual might be remembered by a colleague in the same laboratory. As well the key laboratory personnel, laboratory technicians, who would not normally be chosen to attend an overseas training program will benefit from *in situ* courses. Such courses could also include biosafety assessment and advice on patenting.

The institutes where the courses are held need to be carefully selected to be able to support on-going biotechnology activities and to be able to act as regional centres for specialised commodity research. These centres could attract researchers from other developing countries to upgrade skills in particular commodity research. The commodity research centres in Malaysia are particularly suitable for further development as regional centres of excellence, and expenditure on Malaysia could be justified if such courses include participants from neighbouring countries, thus ensuring spillover benefits.

ACIAR has the following options:

- conduct *in situ* short biotechnology technical courses in developing countries;
- conduct short courses in Australia;
- conduct only project related training.

ACIAR is already undertaking the second and third options. It was seen in the preceding paragraphs that the most effective way of building long term research capacity is by conducting courses in the partner country, in existing research institutions.

#### **Recommendation 15**

**In fulfilling its capacity-building mandate, ACIAR give consideration to funding short *in situ* courses in selected institutions in partner countries which can serve as regional centres of excellence, in order to develop and integrate biotechnology capability into the existing research strengths of institutions in partner countries. Such courses should include the capability to assess the safety of work with genetically manipulated organisms.**

#### **Training (also see preceding section)**

ACIAR already has a long term training scheme—the

John Allwright Fellowship Scheme, which enables about 10 project scientists from developing countries each year to undertake postgraduate studies in Australian universities. Most of these postgraduate programs involve training in biotechnology. Long term training will not be further considered here.

The Crawford Fund for International Agricultural Research established by the Australian Academy of Technological Sciences and Engineering. It makes more widely known the economic and social benefits that accrue from international agricultural research and development. It also encourages greater participation in this research by Australian companies, governments, agencies and scientific organisations, and runs a training scheme to provide short periods of hands-on, practical training for agricultural scientists from developing countries.

The Biotechnology Masterclasses in plant molecular biology are excellent value for money. ACIAR has provided funds for the Crawford Fund Masterclasses of \$100,000 *per annum* for 5 years. It is suggested that the Fund extend and develop the plant molecular biology classes so that they can run for a longer time to enable the inclusion of a plant transformation experiment. The skills gained in this course are generic and can be applied to other plants. If specialist courses are planned, further funding for these courses could be sought for the relevant industry sector by the Crawford Fund. It may also be desirable for participants of courses conducted in Australia to meet possible collaborators in Australian research institutions and to establish linkages with counterpart agencies. Such courses could also be conducted *in situ* in partner country laboratories in order to build capacity.

Other Australian based courses which may be recommended to scientists in partner countries include:

- 'Tropical Plant Tissue Culture and Transformation' course at the Department of Agriculture, University of Queensland;
- 'Genetic Engineering for Decision-Makers' workshop at the CRC for Plant Science, CSIRO Division of Plant Industry.

#### **ASEAN-Australia Economic Cooperation Program**

Under the ASEAN-Australia Economic Cooperation Program (AAECP) Australia provided funding (AUD \$6.04 million) for a joint ASEAN/Australian project

on biotechnology, which began in 1989 and was completed in June 1994. The objectives of the project include the strengthening of biotechnology capability in ASEAN countries.

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## Appendix 1

### List of GMAC Planned Release Proposals

#### Assessed:

- PR-1: Field trial of a live *Salmonella* vaccine to prevent deaths during live sheep export.
- PR-2 To test a recombinant *Rhizobium* strain with a marker gene in a controlled field release experiment.
- PR-3: Inoculation of cattle with a thymidine kinase negative, deletion mutant, infectious bovine rhinotracheitis vaccine virus.
- PR-4: Proposal did not proceed.
- PR-5: National clearance and registration of *Agrobacterium radiobacter* K1026 for control of crown gall disease.
- PR-6: Commercial evaluation of melibiose utilising baker's yeast.
- PR-7: Proposal considered as a Large Scale Proposal
- PR-8: Field release of a live genetically engineered strain of *Pseudomonas* for the purpose of testing a microbial tracking system.
- PR-9: Controlled field release experiment of a *Rhizobium* strain containing a sum plasmid marked with the transposon TN5.
- PR-10: Proposal under assessment by the NHMRC Gene Therapy Committee.
- PR-11 Proposal exempt from GMAC Guidelines.
- PR-12 Synthetic resistance genes to potato leafroll virus 1991.
- PR-13 Proposal still under assessment.
- PR-14 Field evaluation of canola protoplast fusion breeding lines.
- PR-15: Planned release of genetically modified tomatoes in Australia - 1992
- PR-16: Synthetic resistance genes to potato leafroll virus 1993.
- Extension to PR-16: Proposal for the planned release of four lines of genetically engineered potatoes for seed tuber production.
- PR-17: Bt cotton seed increase 1993
- PR-18: Field trial of transgenic potato
- PR-19: Planned release of transgenic carnation for trialing under commercial glasshouse production conditions.
- PR-20: Genetic engineering of cotton for resistance to insect pests.
- PR-21: Proposal did not proceed.
- PR-22: Use of *Aro Salmonella typhimurium* as a vaccine in poultry.
- PR-23: Evaluation of transgenic sugarcane plants.
- PR-24: Contained field growth of grafted apple stock transformed for kanamycin resistance.
- PR-25: Glasshouse trialing of transgenic chrysanthemum under non-PH1 conditions.
- PR-26: Planned release of genetically modified tomatoes in Australia. 1993–1994.
- PR-27: Non-chemical control of bacterial wilt (*Pseudomonas solanacearum*) in North Queensland.
- PR-28: Planned release proposal for trialing transgenic carnation with modified flower colour under non-contained glasshouse conditions.
- Extension to PR28/29: Proposal for extension of PR-28 and PR-29 to an igloo trialing area.
- PR-29: Proposal for planned release of transgenic carnation (ACC synthetase, ACC oxidase, chlorsulfuron resistance) modified for enhanced cut flower vase life.
- PR-30: Planned release of sense suppressed, petal colour modified, transgenic hybrid tea rose containing kanamycin resistance gene, reporter gene and chalcone synthetase gene.
- PR-31: Seed increase of Bt transgenic cotton plants, 1994.
- PR-32: Seed increase and efficacy screening of Roundup tolerant (RT) transgenic cotton plants.
- PR-33. Efficacy evaluation and agronomic selection of Bt transgenic cotton plants 1994/95.
- PR-34: Bt replicated yield and fibre tests and Bt vs. non-Bt yield test 1994/95.
- PR-35: Planned release of transgenic rose (*Rosa X hybrida*) containing kanamycin or chlorsulfuron resistance gene and 'blue' gene (flavonoid 3'5' hydroxylase).
- PR-36: Planned release of transgenic cotton expressing the CryIA(c) or CryIIA delta-endotoxins from *Bacillus thuringiensis*.
- PR-39: Multiple site evaluation of virus resistant potatoes.
- PR-40: Release of herbicide resistant lupins (*Lupinus angustifolius*).
- PR-41: Small scale planned release of modified bovine herpesvirus 1 for intranasal vaccination of cattle.
- PR-42: Field evaluation of low browning potatoes.
- PR-43: Use of transgenic plants to monitor the frequency of Bt resistance in field populations of *Helicoverpa armigera*.

- PR-44: Winter seed increase of transgenic cotton expressing the CryIA(c) delta-endotoxin from *Bacillus thuringiensis*.
- PR-45: Genetic manipulation of rumen bacteria for detoxification of the plant poison fluoracetate. Please note that GMAC advised that this proposal not proceed.

## Appendix 2

### Completed ACIAR Biotechnology Projects

- PN 8367 Research and development of foot-and-mouth disease diagnostic methods in Thailand
- PN 8379 Plant biotechnology for wheat germplasm improvement
- PN 8382 The establishment of improved methods for the diagnosis and control of livestock diseases in Southeast Asia using enzyme-linked immunosorbent assay (ELISA)
- PN 8464 Improved immunological methods for the control of Brucellosis in ruminants
- PN 8501 Biology of *Azolla-Anabaena*
- PN 8517 Improvement of the efficiency of urea fertilisation of rice
- PN 8565 Development of an improved haemorrhagic septicaemia vaccine
- PN 8813 Biotechnology of Barley Yellow Dwarf virus resistance in wheat
- PN 8835 Diagnosis and control of foot-and-mouth disease in Thailand
- PN 8907 The establishment of improved methods for the diagnosis and control of livestock diseases in Southeast Asia using enzyme-linked immunosorbent assay (ELISA), Phase 2
- PN 9015 New approaches to the control of bacterial wilt
- PN 9017 Improved diagnosis and control of peanut stripe virus
- PN 9221 Nucleotide sequence determination of cadang-cadang-like viroids in the Pacific
- Small Project Increased plant production through the treatment of seeds and seedlings with microorganisms

### Appendix 3

#### Current ACIAR Biotechnology Projects

- PN 9049 Evaluation of antigens for vaccination against liver fluke in cattle and buffalo in Indonesia
- PN 9116 Fowl cholera vaccines for Asia
- PN 9117 Management of footrot in small ruminants in Nepal
- PN 9118 Improved methods for the diagnosis and control of bovine Babesiosis and Anaplasmosis in Zimbabwe and Australia
- PN 9205 Improved methods for the diagnosis and prevention of Coryza in China and Australia
- PN 9204 Improved methods in diagnosis, epidemiology, economic and information management in Australia and Thailand
- PN 9301 Studies in the epidemiology and control of bluetongue in China
- PN 9305 Integrated control of citrus pests in China
- PN 9317 Application of plant tissue culture techniques to the propagation and breeding of tea in Indonesia
- PN 9226 Control of papaya ringspot virus in Thailand
- PN 9401 Detection and strain differentiation of plant pathogenic mycoplasma-like organisms in the Australia/Pacific region



## Appendix 4

### List of Cooperative Research Centres Relevant to ACIAR's Programs

**Dr H Cornell, Director**

CRC for Molecular Engineering & Technology:  
Sensing and Diagnostic Technologies  
CSIRO Division of Food Science and Technology  
39-51 (Gate 1) Delhi Rd  
North Ryde NSW 2113  
Phone: (02) 887 8495  
Pager: (02) 963 0637  
Fax: (02) 887 3107

**Professor B E S Gunning, Co-Director**

CRC for Plant Science  
C/RSBS  
Australian National University  
Canberra ACT 0200  
Phone: (06) 249 2330  
Fax: (06) 247 5896

**Dr G A Norton, Director**

CRC for Tropical Pest Management  
Gehrmann Laboratories  
University of Queensland  
Brisbane QLD 4072  
Phone: (07) 365 1851  
Fax: (07) 365 1855

**Professor J B Reid, Director**

CRC for Temperate Hardwood Forestry  
University of Tasmania  
College Road  
Sandy Bay TAS 7005  
Phone: (002) 202 604  
Fax: (002) 202 698

**Dr J Hamblin, Director**

CRC for Legumes in Mediterranean Agriculture  
University of Western Australia  
Nedlands WA 6009  
Phone: (09) 380 2505  
Fax: (09) 380 1140

**Professor J A G Irwin, Director**

CRC for Tropical Plant Pathology  
Level 5, John Hines Building  
University of Queensland QLD 4072  
Phone: (07) 365 2790  
Fax: (07) 365 4771

**Dr G Gartside, Director**

CRC for Hardwood Fibre and Paper Science  
Ian Wark Laboratories  
CSIRO  
Bayview Avenue  
Clayton VIC 3168  
Phone: (03) 542 2244  
Fax: (03) 542 2223

**Dr James Hardie, Director**

CRC for Viticulture  
651 Portrush Road  
Glen Osmond SA 5064  
Phone: (08) 303 9405  
Fax: (08) 33 9449

**Dr L R Piper, Director**

CRC for Premium Quality Wool  
CRC Headquarters  
McClymont Building  
University of New England  
Armidale NSW 2351  
Phone: (067) 73 3609  
Fax: (067) 73 3611

**Dr B Blindon, Director**

CRC for the Cattle and Beef Industry (Meat Quality)  
CRC Headquarters  
McClymont Building  
University of New England  
Armidale NSW 2351  
Phone: (067) 73 3501  
Fax: (067) 73 3500

**Dr Peter Montague, Director**

CRC for Aquaculture  
University of Technology  
Box 123 P O  
Broadway NSW 2007  
Phone: (02) 330 1490  
Fax: (02) 330 1491

**Dr G A Constable**

CRC for Sustainable Cotton Production  
CSIRO Cotton Research Unit  
Wee Waa Road  
Narrabri NSW 2390  
Phone: (067) 93 1105  
Fax: (067) 93 1186

Professor N W Dunn, Director  
CRC for Food Industry Innovation  
Department of Biotechnology  
University of NSW  
Gate 9, High Street  
Randwick NSW 2031  
Phone: (02) 385 2057  
Fax: (02) 385 1015

Dr Ann Hamblin, Director  
CRC for Soil and Land Management  
CSIRO Division of Soils  
Hartley Grove  
URRBRAE SA 5064  
Phone: (08) 303 8670  
Fax: (08) 303 8699

Dr H Tyndale-Biscoe, Director  
CRC for Biological Control of Vertebrate Pest  
Populations  
CSIRO Division of Wildlife and Ecology  
Bellenden Street  
Gungahlin ACT 2601  
Phone: (06) 242 1728  
Fax: (06) 242 9242

Professor C Crossland, Director  
CRC Reef Research Centre  
Kevin Stark Research Building  
James Cook University  
Post Office  
Townsville QLD 4811  
Phone: (077) 81 4976  
Fax: (077) 81 4099

Professor P Cullen, Director  
CRC for Freshwater Ecology  
Water Research Centre  
University of Canberra  
Kirinari Street  
Bruce ACT 2616  
Phone: (06) 201 5167  
Fax: (06) 201 5038

Professor J Kikkawa  
CRC for Tropical Rainforest Ecology and  
Management  
55-65 Greenslopes Street  
Edge Hill  
Cairns QLD 4870  
Phone: (070) 531 661  
Fax: (070) 534 945

Professor Michael Good, Director  
CRC for Vaccine Technology  
Queensland Institute of Medical Research  
The Bancroft Centre  
300 Herston Road  
Brisbane QLD 4029  
Phone: (07) 362 0400  
Fax: (07) 362 0104

A/Professor Charles Webb, Dean of Science  
CRC for Sustainable Development of Tropical  
Savannas  
Northern Territory University  
Darwin NT 0909  
Phone: (089) 46 6550  
Fax: (089) 46 6217

Mr Andrew Crowe, Manager (Acting)  
CRC for Diagnostic Technology  
Office of Research  
Queensland University of Technology  
GPO Box 2435  
Brisbane QLD 4000  
Phone: (07) 864 2197  
Fax: (07) 864 1304

Dr Robert Lawn  
CRC for Sustainable Sugar Production  
James Cook University  
Department of Botany and Tropical Agriculture  
Douglas Campus  
Townsville QLD 4811  
Phone: (077) 81 5763  
Fax: (077) 25 1570

Dr Jim Cullen, Assistant Chief  
CRC for Weed Management Systems  
CSIRO, Division of Entomology  
GPO Box 1700  
Canberra ACT 2601  
Phone: (06) 246 4134  
Fax: (06) 246 4133

Professor David Mainwaring  
CRC for International Food Manufacture and  
Packaging Science  
Pro Vice-Chancellor  
Room 102  
Applied Science Building  
Serpell's Lane and Burwood Road  
Hawthorn VIC 3122  
Phone: (03) 819 8576  
Fax: (03) 819 0834

**Professor John Lovett**  
**CRC for Quality Wheat Products and Processes**  
**Acting Executive Director**  
**GRDC**  
**NFF House**  
**14-16 Brisbane Ave**  
**Barton ACT 2600**  
**Phone: (06) 272 5525**  
**Fax (06) 271 6430**

## Appendix 5

### CHINA

*1. Please list the main facilities, research centres and institutions engaged in agricultural biotechnology research.*

1. Institute of Botany Chinese Academy of Sciences (CAS)
2. Institute of Microbiology (CAS), Beijing
3. Shanghai Institute of Biochemistry
4. National Laboratory of Protein Engineering and Plant Genetic Engineering of the University of Beijing (Beida)
5. Laboratory of Plant Cell Engineering of the Beijing Academy of Agricultural Science
6. Crop Germplasm Resources of the Chinese Academy of Agricultural Sciences (CAAS) Beijing

*2. What biotechnology research activities are conducted in these centres and facilities? (the numbers in the margin refer to the institution in question 1)*

1. BT maize  
potato with maize storage proteins  
alfalfa with sulphur-rich protein
2. caterpillar-resistant tomato
3. disease-resistant cereals  
improving amino acid content of chickpea
4. transgenic tobacco with capsid protein of tobacco mosaic virus
5. new virus-resistant strawberries  
wheat, rice and maize varieties  
disease-resistant tomato
6. BT preparations

*3. What national priorities for biotechnology research have been identified or articulated by the government?*

The China National Centre for Biotechnology Development of the National Commission of Science and Technology coordinates all biotechnology activities, is funding the rice genome project, and is supporting plant and agricultural biotechnologies in more than 120 laboratories.

*4. What national programs in biotechnology have been set up and how much funding has been allocated for the program?*

See main text.

*5. Does the country have any biosafety regulations, protocols or guidelines for biotechnology. If so, what form does this take (e.g. expert committee, consultants, government review, permits). If not, is the country presently drafting any guidelines or regulations?*

No national regulatory oversight or committee for biosafety exists in China.

*6. Does the country have any intellectual property rights for biotechnology. If so, what form does this take (e.g. patents, plant variety rights).*

China became a member of the World Intellectual Property Organisation (WIPO) in 1980. It has patent legislation which excludes living plants and animals but not specifically microorganisms. It covers processes used to produce new varieties.

*7. Is the Country a signatory to the Convention on Biodiversity? If so, does the country have, or is it planning to draft, protocols for biodiversity?*

China has signed and ratified the Biodiversity Convention.

## Appendix 6

### INDONESIA

1. Please list the main facilities, research centres and institutions engaged in agricultural biotechnology research.

1. Centre for the Assessment and Application of Industrial and Agricultural Biotechnology (BPPT);
2. Institute for Research and Development of Agro-based Industry (IRDABI), Ministry of Industry;
3. Laboratory of Plant Biotechnology of CRIFC;
4. Nutrition Research and Development Centre;
5. Research and Development Centre for Biotechnology, Indonesian Institute of Sciences (LIPI);
6. Research Institute for Animal Production;
7. Research Institute for Veterinary Science;
8. Indonesian Biotechnology Research Institute for Estate Crops;
9. Inter University Centre (IUC) on Biotechnology, Institut Teknologi Bandung;
10. Department of Chemical Engineering, Faculty of Engineering, University of Diponegoro;
11. Faculty of Animal Science, Diponegoro University;
12. Laboratory of Biotechnology, Department of Biology, Faculty of Science and Mathematics, Diponegoro University;
13. Faculty of Agriculture, Sebelas Maret University;
14. Faculty of Biology, Jendral Soedirman University;
15. Faculty of Agriculture, Gajah Mada University;
16. Faculty of Biology, Gajah Mada University;
17. Food and Nutrition Development and Research Centre (FANDARC);
18. Inter University Centre for Biotechnology, (IUC-Biotechnology), Gajah Mada University;
19. Jogjakarta Plantation Institute;
20. Faculty of Animal Husbandry, Brawijaya University;
21. Research Institute for Tobacco and Fibre Crops (RITFC);
22. Indonesian Sugar Research Institute;

2. What biotechnology research activities are conducted in these centres and facilities? (the numbers in the margin refer to the institution in question 1)

1. Assessment and application of antibiotic process production;

Assessment and application of plant seedling production;

Assessment and application of vitamin, enzyme and amino acid production;

Production of horticultural plants;

Production of vitamin B-12 (Laboratory scale);

Consultation on antibiotic production;

Consultation on tissue culture for horticultural plants seedling production;

Consultation on vitamin and enzyme production;

Assessment of utilisation of local raw material for antibiotic production;

Assessment of tissue culture for oil palm and somatic and embryo genesis of *Shorea spp.* production;

Assessment of superior fish production and superior livestock production;

Production of horticultural plants;

Consultation on somatic embryo genesis of *Shorea spp.*;

Consultation on superior fish production and superior livestock production;

Secondary metabolites production of *Solanum* plants;

Production of erythromycin, streptomycin, penicillin and vitamin B-12;

Consultation on antibiotic and vitamin production.

2. Fermentation of soybean curd (tahu) whey into microbial cellulosic material, nata de soy;

Quality testing of foods, food products and other agro-industrial products;

R&D on product development and quality improvement for the food industries;

Technical/consulting services to the agro-based industries, especially food, on problem solving, technoeconomics, QMS.

3. Analysis of RFLP of rice and bacterial leaf blight; Molecular technique for plant diseases and pests control;

Cell and tissue culture for rice and soybean improvement;

VAM symbiosis for increasing P fertiliser efficiency and crop yields;

Nitrogen fixation in legumes and cereals;

Bioconversion of plant residues by *Trichoderma* and *Cytophaga*.

4. Nutrition and health benefits of tempe.
5. Fermentation and enzyme technology;

Plant biotechnology;

Animal biotechnology;

- Production of Amyloglucosidase;  
 Production of single cell protein (microbial and microalgal biomass for feed);  
 Production of cattle embryos;  
 Production of plantlets/seedlings of tropical fruits (banana, citrus), horticultural species (ginger), bamboo, forest tree species (*Acacia* and *Albizia*);  
 Training on various aspects of biotechnology e.g. microbial genetics, plant biotechnology (tree improvement), collection and preservation of seeds;  
 Development of EPA/DHA production from fishery industrial wastes;  
 Economic evaluation of amyloglucosidase production;  
 Enhancement of biological nitrogen fixation of soybean in Indonesia, particularly in acid soils of Sumatra;  
 Production of starch hydrolytic enzymes by liquid substrate fermentation;  
 Biotechnology and development of species for industrial timber estate;  
 Exploration and preservation of tropical fruit (citrus).
6. Improvement of low nutrient feed using fermentation technology;  
 Production of mannanase;  
 Embryo transfer;  
 Production of phytase for improving the nutrient quality of rice bran;  
 Production of cassava-protein: fermentation of cassava using *Aspergillus niger*.
  7. Cloning DNA encoding fimbrial antigens of enterotoxigenic *Escherichia coli* causing neonatal diarrhoea in piglets and calves;  
 Production and characterisation of monoclonal antibodies to fimbrial antigens of enterotoxigenic *Escherichia coli*;  
 Production and characterisation of monoclonal antibodies to *Brucella abortus*.
  8. Micropropagation of selected estate crops using cell suspension techniques;  
 Development of molecular markers for disease resistance to *Corynespora* using RFLP/RAPD techniques;  
 Bioconversion of cocoa for flavouring agent production by immobilised cell technique;  
 Production of plantlets of coconut, oil palm and robusta coffee;  
 Advisory services on technology application in estate waste utilisation fermentation, biocontrol of diseases and micropropagation of estate crops;  
 Increasing the resistance of Arabia coffee against nematode;  
 Development of carrier formula for microbes to provide a high viability of bacterial and fungal inoculants;  
 DNA mapping of oil palm resistant to *Ganoderma* disease;  
 Adoption of biotechnological methods for oil palm improvement;  
 Bioreactor micropropagation of elite tea clones through somatic embryogenesis.
  9. Microbial fermentation (11 titles);  
 Enzyme technology (7 titles);  
 Genetic engineering (5 titles);  
 Biological wastewater treatment (7 titles);  
 Short courses on fermentation technology;  
 Short courses on molecular biology;  
 Internship program in genetic engineering, for faculty members of other universities;  
 Internship program in biochemistry, for faculty members of other universities;  
 Internship program in wastewater treatment, for faculty members of other universities;  
 Development of diagnostic probe for HIV;  
 Development of diagnostic probe for *Salmonella*;  
 Treatment for palm oil industry effluent using anaerobic and aerobic process;  
 Design of wastewater treatment plant for the Oberoi Hotel in Bali;  
 Design of wastewater treatment plant for a car manufacturing plant in Jakarta;  
 Microbial transformation of solasodine;  
 Conversion of carbohydrate into high fructose syrup by enzyme reaction;  
 Isolation and characterization of dehalogenating microbes from local resources;  
 Degradation of organochlorine compounds using the dehalogenating microbes.
  10. Fodder yeasts;  
 Lignin (rice straw) decomposition by soil microbes;  
 Nangka powder fermentation to glucose syrup by *Saccharomyces cerevisiae*;  
 Small scale industry training on process technology of tempe and tofu production.
  11. The improvement and the application of bioreproductive technology for increasing sheep productivity;

- Improving productivity of sheep and goat by frozen embryo;  
Embryo transfer in dairy cattle by frozen embryo;  
Training on artificial insemination.
12. Study of media formulation for stimulating callus of *Gnetum gnemon* (mlinjo) seeds;  
Preliminary study for amylase production from recombinant.
  13. Study to obtain salt tolerant rice variety;  
Callus induction to increase secondary metabolite in carrots;  
Protoplast culture in vegetables.
  14. Penicillin production by *Penicillium chrysogenum* strain ATCC 26818 in batch system;  
Production of entomopathogen *Bacillus thuringiensis* through fermentation technology;  
The use of somaclonal variation to produce acid tolerant soybean plant;  
The use of somaclonal variation to produce *Fusarium* toxin tolerant tomato plant;  
Penicillin production by *Penicillium chrysogenum* strain ATCC 261818 in batch system;  
Agriculture research management project.
  15. Purification and detection of Baculovirus with monoclonal antibody;  
Development of monoclonal antibody for detection of CVPD - free citrus seedling stocks;  
PCR for detection of CVPD causing agent in citrus seedlings;  
Transfer of SMZ coat protein gene for development of soybean tolerant to viral infection;  
Production of *Rhizobium* inoculum;  
Technology for *Azolla* mass production;  
Production of oyster mushroom spawn;  
Information, dissemination and training for *Rhizobium* inoculum application;  
Training for integrated pest management (Biological control, etc);  
Tissue culture of garlic for virus free stocks and production of monoclonal antibody for latent viruses.
  16. Search and development of sporeforming bacteria for bioinsecticide;  
Genetic analysis;  
Pollen preservation.
  17. Agricultural Biotechnology;  
Animal Biotechnology;  
Industrial Biotechnology;  
Biopreservative potentials of lactic acid bacteria;  
Cell fusion of *A. niger* and *A. oryzae*;  
Monoclonal antibody for aflatoxin detection;  
Fish fermentation technology;  
Culture collection and their distribution;  
Identification of microbes;  
Bacteriocins as food preservatives.
  18. Genetic analysis of inherited diseases Waardenburg syndrome & Thalassemia;  
Production of monoclonal antibodies against dengue viral antigens and filarial antigens;  
Development of early diagnostic tools by amplification of minicircle DNA using PCR for surra diseases;  
Production of erythromycin;  
Production of bioinsecticide (BT toxin);  
Supporting the university staff development program;  
Supporting the research facility for graduates program;  
Establishment of linkages with industry and institutes;  
Genetic counselling;  
Development of flower biotechnology. A collaborative program between IUC-Biotechnology and Binektra Foundation;  
Prevalence and genetic variation of thalassemia in Indonesia (with MRC Molecular Haematology Unit, IMM Oxford, UK);  
Genetic analysis of Wardenburg Syndrome (with Michigan State University, USA);  
Biodiversity (with International Institute for Biotechnology, Canterbury, UK).
  19. Sugarcane tissue culture;  
Micropropagation of *Durio zibetinus*;  
Micropropagation of *Gnetum gnemon*;  
Micropropagation of *Salacca edulis*.
  20. Development of technology for starter and enzyme production for dairy industry;  
Manipulation of rumen microflora for enhancing cattle production;  
NUFFIC;  
Agricultural Research and Management Project;  
Fish sauce fermentation.
  21. Multiplication of rami through tissue culture;  
Multiplication of tobacco;  
Multiplication of Carna vaccine;  
Callus, plantlets, vaccine for cucumber and zucchini.
  22. Microbial dextranase production using genetic engineering techniques;  
Xanthan gum production from sugarcane products and by-products;

Use of molecular approach to enhance the sugarcane breeding program;  
Wastewater treatment;  
Evaluation of USAB system at Madukismo alcohol factory;  
Test of biocides in sugar factories.

*3. What national priorities for biotechnology research have been identified or articulated by the government?*

See main text, Section 4

*4. What national programs in biotechnology have been set up and how much funding has been allocated for the program?*

National Program on Biotechnology begins in April 95 and is funded to 1999—about 200,000 million Rupiahs.

*5. Does the country have any biosafety regulations, protocols or guidelines for biotechnology. If so, what*

*form does this take (e.g. expert committee, consultants, government review, permits). If not, is the country presently drafting any guidelines or regulations?*

Biosafety regulation comprises of ad hoc expert committees and the Directorate of Quarantine or the National Research Council. The committees report and make recommendations to the relevant Minister.

*6. Does the country have any intellectual property rights for biotechnology? If so, what form does this take (e.g. patents, plant variety rights)?*

There is no patent protection legislation for biotechnology in Indonesia.

*7. Is the country a signatory to the Convention on Biodiversity? If so, does the country have, or is it planning to draft, protocols for biodiversity?*

Yes, Indonesia has ratified the Biodiversity Convention.



## Appendix 7

### MALAYSIA

1. Please list the main facilities, research centres and institutions engaged in agricultural biotechnology research.

1. University: Universiti Kebangsaan Malaysia (UKM), University Malaya (UM);
2. Universiti Sains Malaysia (USM), Universiti Pertanian Malaysia (UPM);
3. Universiti MAS new Sarawak campus has just been established;
4. Institute: Forest Research Institute of Malaysia (FRIM);
5. Palm Oil Research Institute of Malaysia (PORIM);
6. Rubber Research Institute of Malaysia (RRIM);
7. Malaysian Agricultural Research and Development Institute (MARDI);
8. Veterinary Research Institute;

2. What biotechnology research activities are conducted in these centres and facilities?

Very broad including animals, flowers, fruits, rice, vaccine production, embryo transfer, tissue culture and waste technology. Malaysia's new policy is not to open new land for agriculture to increase production but to utilise idle land and increase yield by more high yielding strains.

3. What national priorities for biotechnology research have been identified or articulated by the government?

The National Biotechnology Working Group have identified the following priorities for plant biotechnology:

- in vitro tissue culture
- DNA marker technology
- genetic engineering
- cyopreservation
- protein studies

Priorities for animal biotechnology set by the Animal Working Group include:

- Animal nutrition and production biotechnology
  - enzymes and microbial additives
  - growth promotants and regulators
  - manipulation of rumen ecosystems
  - bioprocessing of low quality feed
- Animal breeding and reproduction biotechnology
  - conservation of genome DNA

- conservation of sperm and embryos
- reproductive biotechnologies
- DNA recombinant technology including transgenesis
- Animal health biotechnology
  - development of diagnostic reagents and kits
  - development of vaccines
  - food safety
- Fish production and health biotechnology
  - genetic improvement of selected foods and ornamental fish
  - disease diagnosis and control
  - conservation of genetic resources
  - fish as a sensor of pollution

4. What national programs in biotechnology have been set up and how much funding has been allocated for the program?

The 6th Malaysian Plan (1991–1995) allocated \$6 million Ringgit to agriculture. Malaysia is setting up a National Biotechnology Directorate headed by Professor Latif which has a budget of \$100 million Ringgit over 3 years. The Directorate, under the Ministry of Science and Technology and the Environment will take over all the functions of the National Biotechnology Working Group and establish a National Biotechnology Program. The objectives of the Directorate are:

- to raise the reputation of Malaysian biotechnology so as to attract national and international investment;
- to encourage Malaysian industry to increase its investment in biotechnology R & D; and
- to provide an optimal infrastructure for the commercialisation of biotechnology R & D.

Priority investment areas:

- diagnosis, vaccines and other health areas
- plant tissue culture scale up
- biotechnology of chemicals
- natural products screening and development
- environmental biotechnology

5. Does the country have any biosafety regulations, protocols or guidelines for biotechnology. If so, what form does this take (e.g. expert committee, consultants, government review, permits). If not, is the country presently drafting any guidelines or regulations?

Malaysia is now in the process of making guidelines. There is a biosafety committee which is being incorporated into the Government (Ministry of Science,

Technology & Environment), and will report to the Biotechnology Directorate. Previously this function was carried out by the National Biotechnology Working Group.

*6. Does the country have any intellectual property rights for biotechnology. If so, what form does this take (e.g. patents, plant variety rights).*

Malaysia does not specifically have any intellectual property rights for biotechnology, but is covered by an Intellectual Property Rights agreement covering all IPR. Malaysia will be looking to have an IPR for

biotechnology at some stage—Malaysia belongs to the World Intellectual Property Organisation (WIPO). Intellectual Property comes under the Ministry of Domestic Trade & Consumer Affairs.

*7. Is the Country a signatory to the Convention on Biodiversity? If so, does the country have, or is it planning to draft, protocols for biodiversity?*

Yes, Malaysia was one of the first to sign Convention on Biodiversity and is planning to draft protocols for biodiversity but does not currently have one.

## Appendix 8

### PHILIPPINES

1. Please list the main facilities, research centres and institutions engaged in agricultural biotechnology research.

*Within the University of the Philippines at Los Banos*

1. Institutes of Biotechnology and Microbiology (BIOTECH);
2. Institute of Plant Breeding;
3. College of Veterinary Medicine;
4. Institute of Animal Sciences;
5. Dairy Training & Research Institute;
6. Institute of Food Science;
7. National Crop Protection Center;
8. Institute of Biological Sciences;
9. PHILRICE;

*Under the Department of Science and Technology*

10. Industrial Technology and Development Institute;

*Other State Colleges and Universities*

11. Central Luzon State University;
12. Visayas State College of Agriculture;
13. Benguet State University;
14. Central Mindanao University;
15. University of Southern Mindanao;
16. Mariano Marcos State University.

2. What biotechnology research activity are conducted in these centres and facilities? (the numbers in the margin refer to the institution in question 1)

1. Plant tissue culture of legumes and ornamental, crop improvement, vegetables and fruit, plantation crops and *Rhizobium*;
2. Plant tissue culture of legumes and ornamentals, crop improvement, vegetables and fruit, plantation crops and *Rhizobium*;
3. Vaccines, diagnostics;
4. In-vitro fertilisation, embryo transfer;
5. Cheese and milk products;
6. Fermentation, food processing;
7. Integrated pest management;

8. Genetic engineering—basic aspects;
9. Transgenic rice;
10. Mushrooms;
11. Livestock-embryo transfer; fisheries—tilapia breeding, tissue culture;
12. Biofertiliser, tissue culture;
13. Tissue culture;
14. Tissue culture;
15. Tissue culture;
16. Tissue culture.

3. What national priorities for biotechnology research have been identified or articulated by the government?

The Philippines Agricultural Agenda (1995-2000) is due for approval. This document articulates priorities and programs for biotechnology.

4. What national programs in biotechnology have been set up and how much funding has been allocated for the program?

The Philippines Agricultural Agenda (1995-2000) is due for approval. This document articulates priorities and programs for biotechnology.

5. Does the country have any biosafety regulations, protocols or guidelines for biotechnology. If so, what form does this take (e.g. expert committee, consultants, government review, permits). If not, is the country presently drafting any guidelines or regulations?

The Philippines has biosafety guidelines and these are implemented by an expert committee.

6. Does the country have any intellectual property rights for biotechnology. If so, what form does this take (e.g. patents, plant variety rights).

The Philippines has IPR for biotechnology in the form of patents and plant variety rights.

7. Is the Country a signatory to the Convention on Biodiversity? If so, does the country have, or is it planning to draft, protocols for biodiversity?

The Philippines has signed and ratified the Convention and has an existing protocol.

## Appendix 9

### THAILAND

*1. Please list the main facilities, research centres and instructions engaged in agricultural biotechnology.*

1.1. Universities in Thailand engaged in agricultural biotechnology research are listed as follows:

Chulalongkorn University  
Kasetsart University  
Mahidol University  
Khon Kaen University, Khon Kaen  
Chiang Mai University, Chiang Mai  
Srinakharinwirot University Prasammit Campus  
Prince of Songkla University Hat Yai Campus  
Burapar University  
Naresuan University, Phitsanulok  
King Mongkut's Institute of Technology Thonburi  
King Mongkut's Institute of Technology Lat Krabang  
Maejo Institute of Agricultural Technology, Chiang Mai

Research activities are dissipated among various departments and faculties in each university.

1.2. Some government agencies are also engaged in agricultural biotechnology research. These are as follows:

- Ministry of Agriculture and Cooperatives
  - Department of Agriculture
  - Department of Fisheries
  - Department of Livestock Development
  - The Royal Forest Department
- Ministry of Science, Technology and Environment
  - National Centre for Generic Engineering and Biotechnology, National Science and Technology Development Agency
  - Thailand Institute of Scientific and Technological Research

*2. What biotechnology research activities are conducted in these centres and facilities?*

- Plant varietal improvement
- Seed/seeding improvement
- Pest control
- Postharvest technology
- Animal breed improvement
- Embryo transfer

- Animal health improvement
- Feed improvement
- Marine biotechnology
- Mushroom cultivation
- Algal Production
- Agricultural waste utilisation
- Development of biofertiliser
- Development of biopesticide

*3. What national priorities for biotechnology research have been identified or articulated by the government?*

- Plant and plant product improvement
- Animal and animal product improvement
- Rural development and small farmers
- Sustainable development
- Health Improvement
- Novel products and industrial process improvement

*4. What national programs in biotechnology have been set up and how much funding has been allocated for the program.*

National centre for Genetic Engineering and Biotechnology (NCGEB), National Science and Technology Development Agency, is responsible in setting up the national programs in biotechnology for Thailand. This year NCGEB has about 100 million baht allocated from the government and this will increase by around 10% each year.

*5. Does the country have any biosafety regulations, protocols or guidelines for biotechnology. If so, what form does this take (e.g. expert committee, consultants, government review, permits). If not, is the country presently drafting any guidelines or regulations.*

The drafting of Biosafety guidelines was completed in 1992. The guidelines cover guidelines for laboratory practice and the releases of genetically modified organisms (GMOs) into the environment. The National Biosafety Committee (NBC) was established in 1993 and also the Institutional Biosafety Committee (IBC) at various universities, government departments, research institutes, regulatory agencies as well as private agencies was strongly recommended for establishment.

*6. Does the country have any intellectual property rights for biotechnology. If so, what form does this take (e.g. patents, plant variety rights)?*

Plant variety protection act is in the approval process by the government.

*7. Is the country a signatory to the Convention on Biodiversity. If so, does the country have or is it planning to draft protocols for biodiversity?*

It is a signatory of the Convention. Our government is still considering whether to ratify the Convention on Biodiversity.

## Appendix 10

### VIETNAM

*1. Please list the main facilities, research centres and institutions engaged in agricultural biotechnology research.*

(Facilities 1–9 belong to the Ministry of Agriculture and Food Industry (MAFI))

1. Agricultural Genetic Institute (AGI)
2. National Institute of Agricultural Science and Technology (INSA)
3. Postharvest Technology Institute (PTI)
4. National Institute of Plant Protection (NIPP)
5. Plant Protection Department (PPD)
6. National Institute of Veterinary Research (NIVR)
7. Central Veterinary Medicinal Research Enterprise (CVMRE)
8. National Institute of Animal Husbandry (NIAH)
9. Institute of Agricultural Science of South Vietnam (IAS)
10. Biotechnology Institute belonging to the National Technology and Natural Science Centre (NTNCS)
11. Tropical Biology Institute in South Vietnam (TBI)
12. Nha Trang Ocean Research Institute (ORI)
13. Mushroom Research Centre, Biology Faculty, National University of Hanoi (NUH)

*2. What biotechnology research activity are conducted in these centres and facilities?*

1. AGI: research on molecular genetic technology and plant gene technology, plant gene-bank and plant technology;
2. INSA: research on microorganism and microorganism gene-bank for plant fertiliser (fixed microorganic fertiliser, nitrogen, an easily digested fertiliser phosphorus, fertiliser to stimulate growth); research plant gene technology, transplanting cell and plant gene-bank;
3. PTI: research on enzyme technology, biochemistry and entomology technology for rice, maize, rootcrops, peas, beans—conservation and processing postharvest agricultural produce with a view to increasing nutrition;
4. NIPP: research biotechnology to produce all kinds of medicine to prevent insects in the field to protect crops: rice, maize, vegetables and industrial crops;
5. PPD: research biotechnology to produce medicine to protect plants and animals;

6. NIVR: research on microorganic immunisation technology for animals; research to produce vaccine to protect and prevent disease in livestock;
7. CVMRE: research to produce veterinary medicine, produce all kinds to vaccine to protect and prevent disease in livestock;
8. NIAH: research on biotechnology of animals and animal gene-bank;
9. IAS: research on biotechnology for plants and plant gene; animal biotechnology and animal gene;
10. NTNCS: research on plant biotechnology and plant gene-bank; research on animal biotechnology and animal gene-bank, mainly for cattle;
11. TBI: research on plant biotechnology and transplant cell technology; research the technology of all kinds of medicine production to prevent insects in plants; research on enzyme technology for processing agricultural produce;
12. ORI: research on biotechnology to exploit the sea's natural resources.

*3. What national priorities for biotechnology research have been identified or articulated by the government?*

A (translated) extract from Government Resolution number 18/CP of 11 March 1994, on 'Biotechnology Development in Vietnam to year 2010' is copied below:

III. Content of the Biotechnology Development in Vietnam to the year 2010

- 1) Biotechnology to serve agriculture, forestry and fisheries development;
- 2) Biotechnology to serve health of the people;
- 3) Biotechnology to serve protection of living environment and natural bioresources;
- 4) Biotechnology to serve other industries;
- 5) Building up scientific and technological capabilities in the field of biotechnology;
- 6) Building up of biotechnology industry.

*4. What national programs in biotechnology have been set up and how much funding has been allocated for the program?*

A (translated) extract from the five year program KC-08 (1991–1995) is copied below. Dr Nguyen Thien Luan, Vice Minister, MAFI, is chairman of this program. Details of funds are not available.

IV. Biotechnology Program—12 main topics

- 1) Research on technological method for cell duplication in fruit crops, forest trees and medical plants;

- 2) Use cell technology in creating high resistant crop varieties for droughts, cold and hot weather;
- 3) Research to complete technology on new breeds of cattle and increased growth of fish;
- 4) Technology to redevelop DNA variety which has high resistance, high productivity and good quality;
- 5) Research and classify new varieties in microbiology to produce fertiliser to exploit biotechnology and food stuff industry;
- 6) Research and apply biotechnology to produce biology production in order to protect plants and conserve and process agricultural products;
- 7) Research and apply the good varieties to increase protein in foodstuffs;
- 8) Research new varieties of rare mushrooms and methods to stop disease of these mushrooms in production;
- 9) Research production technology and apply 'proteinaza-inhibito' in medicine and agriculture;
- 10) Research enzyme technology to process the products which have high protein and amino acid for human and animals;
- 11) Research product technology which have high nutrition for human and animals;
- 12) Research to improve tetradoxin products technology.

A Committee on Biotechnology has been established

by the National Assembly. This committee will assess policy in the use of Biotechnology in Vietnam.

*5. Does Vietnam have any biosafety regulations, protocols or guidelines for biotechnology. If so, what form does this take (e.g. expert committee, consultants, government review, permits). If not, is Vietnam presently drafting any guidelines or regulations?*

The government has an ordinance to protect and guarantee animals and plants and an ordinance for veterinary research. The Plant Protection Department and Veterinary Research Department control imports of plants and animals.

*6. Does Vietnam have any intellectual property rights for biotechnology. If so, what form does this take (e.g. patents, plant variety rights)?*

The Parliament Committee of the National Assembly has promulgated a decree on protection of all intellectual property rights. This decree has two ordinances: (1) protection of inventions; and (2) protection of utilities solution. Protection is by patents.

*7. Is Vietnam a signatory to the Convention on Biodiversity? If so, does Vietnam have, or is it planning to draft, protocols for biodiversity?*

Vietnam is a signatory and has also ratified the Convention.

## Appendix 11

### Summary of International Agricultural Biotechnology Initiatives

NAME (host institution)	PRIORITIES	AGRICULTURAL REGION / FOCUS (crop / livestock)	COUNTRY FOCUS
<b>CROP RESEARCH PROGRAMMES</b>			
Agricultural Biotechnology for Sustainable Productivity, ABSP (Michigan State University)	<ul style="list-style-type: none"> <li>• genetic engineering of crops for pest/disease resistance</li> <li>• development of micropropagation systems</li> <li>• integration of biotechnology within a general agriculture and business framework</li> <li>• biosafety</li> <li>• IPR</li> <li>• technology transfer</li> </ul>	maize potato coffee sweet potato cucurbits banana pineapple	Costa Rica Egypt Kenya Indonesia
Bean/Cowpea Collaborative Research Support Program, B/C CRSP (various US universities)	<ul style="list-style-type: none"> <li>• control of pests and diseases</li> <li>• increase crop yields</li> <li>• increase nutritional quality</li> </ul>	bean cowpea	Africa Latin America & the Caribbean
Biotechnology-Assisted Breeding to Reduce Pesticide Use in Potatoes (CIP)	<ul style="list-style-type: none"> <li>• durable resistance to pests and diseases</li> <li>• integrated pest management</li> </ul>	potato	international
Centre for the Application of Molecular Biology to International Agriculture, CAMBIA	<ul style="list-style-type: none"> <li>• novel biotechnologies and methods for agricultural innovation</li> <li>• genetic markers and diagnostics apomixis</li> </ul>	rice cassava bean agroforestry	international Latin America & the Caribbean
CATIE - Biotechnology Unit	<ul style="list-style-type: none"> <li>• enhance regional program capabilities</li> <li>• genetic improvement of tropical crops</li> </ul>	banana/plantains coffee cocoa roots and tubers	
CIAT - Biotechnology Research Unit	<ul style="list-style-type: none"> <li>• increasing the efficiency of CIAT strategy research</li> <li>• institutional development of biotechnology</li> </ul>	cassava common bean rice tropical forages	international
CIRAD - Plant Breeding Division	<ul style="list-style-type: none"> <li>• develop genetically improved crops</li> </ul>	cotton rice sorghum tropical perennials tropical fruits forestry	international



<b>Feathery Mottle Virus Resistant Sweet Potato for African Farmers (USAID)</b>	<ul style="list-style-type: none"> <li>• human resource development</li> <li>• production of virus-resistant, African varieties of sweet potato</li> <li>• enhance capacity in biosafety regulation of transgenic crop plants</li> <li>• export of transgenic sweet potato to Africa for field testing</li> <li>• technology transfer</li> </ul>	sweet potato	Kenya
<b>ICGEB - Plant Biotechnology Sub-Programme</b>	<ul style="list-style-type: none"> <li>• capacity building</li> <li>• genetically improved rice</li> </ul>	rice	international
<b>ICRISAT - Biotechnology</b>	<ul style="list-style-type: none"> <li>• support and complement conventional crop improvement programs at ICRISAT</li> </ul>	sorghum pearl millet groundnut chickpea pigeonpea	international
<b>IIRSDA - Plant Biotechnology Program</b>	<ul style="list-style-type: none"> <li>• conservation and characterisation of yam germplasm</li> <li>• micropropagation and genetic improvement of yam and other crops</li> </ul>	yam African eggplant	Sub-Saharan Africa
<b>IITA - Biotechnology Research Unit</b>	<ul style="list-style-type: none"> <li>• tackle recalcitrant problems in crop improvement</li> <li>• enhance national research capabilities</li> </ul>	cowpea yam cassava banana/plantain	Sub-Saharan Africa
<b>International Laboratory for Tropical Agricultural Biotechnology, ILTAB (Scripps Research Institute)</b>	<ul style="list-style-type: none"> <li>• genetically engineered food crops with virus resistance</li> </ul>	rice cassava tomato sugarcane	international
<b>International Program on Rice Biotechnology (Rockefeller Foundation)</b>	<ul style="list-style-type: none"> <li>• rice genetic improvement</li> <li>• capacity building</li> </ul>	rice	international
<b>International Service for the Acquisition of Agri-biotech Applications, ISAAA (Cornell University)</b>	<ul style="list-style-type: none"> <li>• acquisition and transfer of near-term applications of agricultural biotechnology applications, particularly proprietary technology</li> <li>• biosafety</li> </ul>	vegetables fruits field crops agroforestry	international
<b>ODA Plant Sciences Research Programme (University of Wales)</b>	<ul style="list-style-type: none"> <li>• genetically improved crops</li> </ul>	cereals roots & tubers legumes oilseeds fruit & vegetables fibres	Côte d'Ivoire Niger India Nepal Pakistan Peru

Reducing Maize Losses to Insect Pests by Enhancing Host Plant Resistance with <i>Bacillus thuringiensis</i> Toxin Genes (CIMMYT)	<ul style="list-style-type: none"> <li>• enhanced insect-resistance maize germplasm</li> </ul>	maize	international
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Regional Program of Biotechnology for Latin American (several UN organisations)	<ul style="list-style-type: none"> <li>• collaborative research projects</li> <li>• training</li> </ul>	maize potato sugarcane	Latin American & the Caribbean
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### LIVESTOCK RESEARCH PROGRAMMES

CIRAD - Animal Production Division	<ul style="list-style-type: none"> <li>• development of heat-stable vaccines through genetic engineering</li> <li>• improved diagnostic tests</li> <li>• determination of genetic resistance to diseases</li> </ul>	cowdriosis dermatophilosis rinderpest peste des petits ruminants mycoplasmosis trypanosomiasis	international
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International Laboratory of Molecular Biology for Tropical Disease Agents, ILMB (University of California)	<ul style="list-style-type: none"> <li>• live recombinant virus vaccines for animal diseases</li> <li>• technology transfer</li> </ul>	rinderpest bovine virus diarrhoea equine influenza peste des petits ruminants foot and mouth disease vesicular stomatitis virus	international
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ILRAD - Tick-Borne Diseases Program	<ul style="list-style-type: none"> <li>• novel vaccines</li> <li>• improve current control methods</li> </ul>	theileriosis cowdriosis anaplasmosis babesiosis	international
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ILRAD - Trypanosomiasis Program	<ul style="list-style-type: none"> <li>• improve diagnosis and parasite characterisation</li> <li>• novel vaccines</li> <li>• breeding for genetic resistance</li> </ul>	trypanosomiasis	international
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Indo-Swiss Collaboration in Biotechnology, ISCB (Swiss Federal Institute of Technology)	<ul style="list-style-type: none"> <li>• capacity building</li> <li>• animal disease diagnostics and vaccines</li> <li>• biopesticides</li> </ul>	foot and mouth disease contagious caprine pleuropneumonia	India
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Small Ruminant Collaborative Research Support Program, SR CRSP - Animal Health Component (Washington State University)	<ul style="list-style-type: none"> <li>• improve the efficiency of milk and meat production from small ruminants</li> <li>• virus-vectored vaccines for sheep and goats</li> </ul>	heartwater contagious caprine pleuropneumonia Nairobi sheep disease	Kenya Indonesia Bolivia
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Tickborne Diseases Vaccine Development Program (University of Florida)	<ul style="list-style-type: none"> <li>• development and commercialisation of improved vaccines and diagnostic tests</li> </ul>	heartwater anaplasmosis babesiosis	Egypt Mali Kenya Zimbabwe Thailand Costa Rica Mexico
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## ADVISORY PROGRAMMES

Biotechnology Advisory Commission, BAC (Stockholm Environment Institute)	<ul style="list-style-type: none"> <li>• review biotechnology projects involving field testing and/or the planned introduction of genetically modified organisms</li> </ul>		international
Intermediary Biotechnology Service, IBS (ISNAR)	<ul style="list-style-type: none"> <li>• biotechnology research program management and policy formulation</li> <li>• country reviews</li> <li>• identify international program expertise</li> </ul>		international
Support to Agricultural Biotechnology Policies (IICA)	<ul style="list-style-type: none"> <li>• biosafety, IPR</li> <li>• industry development</li> </ul>		Latin America & the Caribbean

## NETWORKS

African Biosciences Network - Sub-Network for Biotechnology, ABN-BIOTECHNET (University of Nigeria)	<ul style="list-style-type: none"> <li>• genetically improved crops and farm animals</li> <li>• disease control through new vaccines</li> <li>• capacity building</li> </ul>		Africa
Asia Network for Small-Scale Agricultural Biotechnologies, ANSAB	<ul style="list-style-type: none"> <li>• plant tissue culture</li> <li>• biopesticides</li> <li>• biofertilisers</li> <li>• mushroom technology</li> </ul>	potato kapok tree rice mushroom	Asia
Asian Rice Biotechnology Network, ARBN (IRRI)	<ul style="list-style-type: none"> <li>• DNA fingerprinting of pests and pathogens</li> <li>• low-cost marker-aided selection</li> <li>• transgenic rice</li> </ul>	rice	Asia
Phaseolus Bean Advanced Biotechnology Research Network, BARN (CIAT)	<ul style="list-style-type: none"> <li>• constraint identification</li> <li>• technology transfer</li> <li>• information exchange</li> </ul>	beans	international
Cassava Biotechnology Network, CBN (CIAT)	<ul style="list-style-type: none"> <li>• stimulate cassava biotechnology research on priority topics</li> <li>• integrate priorities of small-scale farmers, processors, and consumers in cassava biotechnology research planning</li> <li>• information exchange</li> </ul>	cassava	international

Technical Cooperation Network on Plant Biotechnology, REDBIO (FAO/RLAC)	<ul style="list-style-type: none"> <li>• generation, transfer and application of plant biotechnology</li> <li>• national and regional policies</li> <li>• information exchange</li> </ul>	vegetables roots & tubers cereals	Latin American & the Caribbean
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## DONOR AGENCIES

Australian Centre for International Agricultural Research, ACIAR	<ul style="list-style-type: none"> <li>• use biotechnology wherever appropriate as a research tool within any of ACIAR's projects</li> </ul>		international
DGIS Special Programme Biotechnology and Development Cooperation (Ministry of Foreign Affairs, The Netherlands)	<ul style="list-style-type: none"> <li>• improve developing-country access to biotechnology, with special emphasis on small-scale producers and women</li> <li>• technical cooperation</li> <li>• international collaboration and coordination</li> </ul>	"orphan" commodities cassava	Colombia India Kenya Zimbabwe
FAO/AGP Programme on Plant Biotechnology (Food and Agriculture Organisation of the United Nations)	<ul style="list-style-type: none"> <li>• information dissemination and cooperation</li> <li>• advisory services</li> <li>• capacity building</li> <li>• promote research, technology transfer and adoption</li> </ul>	rice roots & tubers horticulture industrial crops	international
United Nations Development Programme	<ul style="list-style-type: none"> <li>• productive and sustainable agriculture</li> </ul>	food crops cash crops livestock	international
World Bank	<ul style="list-style-type: none"> <li>• invest in biotechnology as a contribution to economic development in World Bank member countries</li> </ul>		international

CATIE = Centro Agronomico Tropical de Investigacion y Ensenanza; CIAT = International Centre for Tropical Agriculture; CIMMYT = International Centre for Maize and Wheat Improvement; CIP = International Potato Centre; CIRAD = Centre de coopération internationale en recherche agronomique pour le développement; FAO/AGP = UN Food and Agriculture Organization, Plant Production and Protection Division; FAO/RLAC = UN Food and Agricultural Organisation, Regional Office for Latin America and the Caribbean; ICGEB = International Centre for Genetic Engineering and Biotechnology; ICRISAT = International Crop Research Institute for the Semi-Arid Tropics; IICA = Interamerican Institute for Cooperation in Agriculture; IIRSDA = Institut international de recherche scientifique pour le développement en Afrique; IITA = International Institute for Tropical Agriculture; ILRAD = International Laboratory for Research on Animal Diseases; IRRI = International Rice Research Institute; ISNAR = International Service for National Agricultural Research; ODA = Overseas Development Administration (UK); USAID = United States Agency for International Development.

Note: For the purpose of the survey, ACIAR was considered as a donor agency as it does not conduct its own research, but arranges collaborative research projects between scientists working in existing research institutions in Australia and in the overseas partner countries.

## Appendix 12

### CONVENTION ON BIOLOGICAL DIVERSITY

(Rio de Janeiro, 5 June 1992) - Updated 20 April 1995

Developing countries within ACIAR's mandate excluding South and Latin American,  
and West African countries

Entry into force: 29 December 1993.

Participant	Signature	Ratification Accession(a) Acceptance (A) Approval(AA)
Australia	5 Jun 1992	18 Jun 1993
Bangladesh	5 Jun 1992	3 May 1994
Burundi	11 Jun 1992	
Cambodia		9 Feb 1995(a)
China	11 Jun 1992	5 Jan 1993
Cook Islands	12 Jun 1992	20 Apr 1993
Fiji	9 Oct 1992	25 Feb 1993
India	5 Jun 1992	18 Feb 1994
Indonesia	5 Jun 1992	23 Aug 1994
Jordan	11 Jun 1992	12 Nov 1993
Kenya	11 Jun 1992	26 Jul 1994
Kiribati		16 Aug 1994(a)
Malaysia	12 Jun 1992	24 Jun 1994
Maldives	12 Jun 1992	9 Nov 1992
Micronesia	12 Jun 1992	20 Jun 1994
Mongolia	12 Jun 1992	30 Sep 1993
Myanmar	11 Jun 1992	25 Nov 1994
Nepal	12 Jun 1992	23 Nov 1993
Pakistan	5 Jun 1992	26 Jul 1994
Papua New Guinea	13 Jun 1992	16 Mar 1993
Philippines	12 Jun 1992	8 Oct 1993
Samoa	12 Jun 1992	9 Feb 1994
Solomon Islands	13 Jun 1992	
Sri Lanka	10 Jun 1992	23 Mar 1994
Tanzania	12 Jun 1992	
Thailand	12 Jun 1992	
Tuvalu	8 Jun 1992	
Vanuatu	9 Jun 1992	25 Mar 1993
Vietnam	28 May 1993	16 Nov 1994
Zambia	11 Jun 1992	28 May 1993
Zimbabwe	12 Jun 1992	11 Nov 1994