AUSTRALIAN BIOTECHNOLOGY 2000

a national strategy

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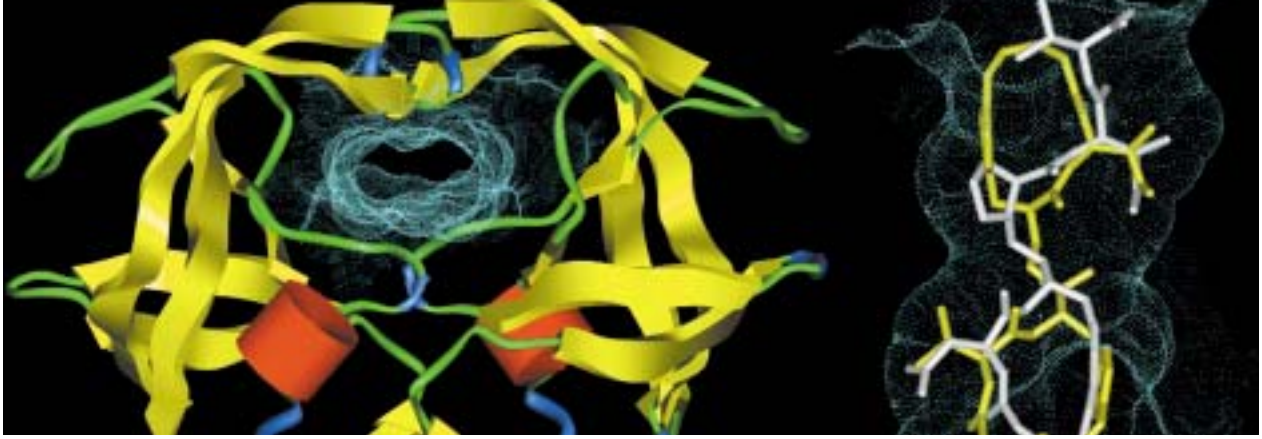
a national strategy



ISR 2000/036

ISBN 0 642 72028 2

Design and production: Big Island Graphics and Corporate Communications.

Printing: Paragon Printers Australasia

Contents

On behalf of my colleagues on the Commonwealth Biotechnology Ministerial Council, I am pleased to present the National Biotechnology Strategy which outlines the Government's vision and support for biotechnology.

Biotechnology is a key technology of the future. It presents enormous opportunities as well as great challenges. Biotechnology holds the promise of improved health and welfare for all Australians through better understanding of disease, improved diagnosis, and treatment with more specific biopharmaceutical products. Biotechnology, including the genetic modification of agricultural and food products, also has the potential to deliver productivity, competitiveness and sustainability benefits to Australia. The technology offers improved resistance to insects and disease, and new uses for agricultural products, improved food qualities, reduced environmental impact and bioremediation are all possible.

Australia has developed world class strengths in biotechnology-related medical, agricultural and environmental research. We must build on these strengths for the responsible development and management of biotechnology in Australia. Through biotechnology we are developing innovative products, building fast-growing enterprises, attracting international investment and creating high value employment. The Government will work to ensure that Australians have access to the skills and knowledge they need to keep pace with this global revolution.

We believe it is also important to safeguard the health of our community and the environment and that Australia is well served by a range of regulators who are working together to provide assurance that biotechnology is safe for our country.

The Government ensures rigorous human health and environmental assessment of GMO releases, and will undertake research to improve the knowledge base and manage risks in the field.

The National Biotechnology strategy provides a framework for Government, working with key stakeholders, to capture the benefits of biotechnology development for Australia. The strategy addresses the present situation in a rapidly changing environment, and will be a living document, able to address new challenges as they arise.

Ministerial Introduction

Senator The Hon Nick Minchin

Chairman

Biotechnology Ministerial Council and Minister for Industry Science and Resources

Senator The Hon Robert Hill

Minister for the Environment and Heritage

The Hon Warren Truss

Minister for Agriculture, Fisheries and Forestries

The Hon Dr Michael Wooldridge

Minister for Health and Aged Care

The Hon Dr David Kemp

Minister for Education, Training and Youth Affairs

Foreword by the Biotechnology Consultative Group

The Biotechnology Consultative Group (BIOCOG) supports the Government's vision to develop a National Biotechnology Strategy and has contributed to its formulation over the last year. The issues which require the greatest attention include:

- Ensuring effective regulation of biotechnology research and application.
- Providing balanced information to the public on biotechnology issues.
- Addressing the critical gap in early stage funding and management and the creation of competitive biotech clusters.

Global biotechnology innovation and growth continues to accelerate. The United States, Canada, UK, and Germany, for example, are reaping tremendous benefits from major government programs and growing private sector commitments to develop industries utilising biotechnology. Effective commercialisation of the technologies developed in Australia is necessary to generate a return from our investment and participate in the global biotechnology marketplace. The potential rewards are enormous: one biotech-based pharmaceutical, erythropoietin, generated world-wide market sales in excess of $A5 billion in 1999, equivalent to the total world export sales of Australian gold in that year.

We believe that biotechnology-based technologies and industries will create new high value employment, generate health and environmental benefits, and provide a strong basis for continued economic growth. These are important priorities for Government. A requisite step will be enhanced cooperation between the Commonwealth, the States, research organisations, and the private sector.

Tony Bates
Chair,
Biotechnology Consultative Group

The Biotechnology Consultative Group was formed in 1999 to advise Biotechnology Australia and the Commonwealth Biotechnology Ministerial Council on the development of the National Biotechnology Strategy. The Group consists of 22 members from the research and business sectors, including ethicists and nutritionists.

Government's Vision for Australian Biotechnology

Consistent with safeguarding human health and ensuring environmental protection, that Australia capture the benefits of biotechnology for the Australian community, industry and the environment.

This vision, which is based on the responsible use of biotechnology to drive economic and community benefit, is supported by the Government's goals for biotechnology which are:

- To ensure that in research into, and in applications of biotechnology
  - human health and the environment are safeguarded, in particular through a rigorous, efficient and transparent system of regulation for gene technology research and for genetically modified organisms and products; and
  - the highest ethical standards are observed.
- To ensure that the community has access to quality information about biotechnology, the potential risks and benefits of its applications, the ethical issues they raise, and has confidence in the way risks are assessed and managed
  - and that it can contribute to public policy in this area.
- To enhance the economic and community benefits of biotechnology through
  - an internationally competitive environment for investment and enterprise development;
  - stronger links between the biotechnology research sector and industries that apply biotechnology; and
  - better management of intellectual property.
- To maintain and develop the infrastructure for generating biotechnology applications through
  - productive investment in biotechnology research and development;
  - world class education in biotechnology;
  - secure access to genetic and biological resources; and
  - conserving genetic and biological resources.

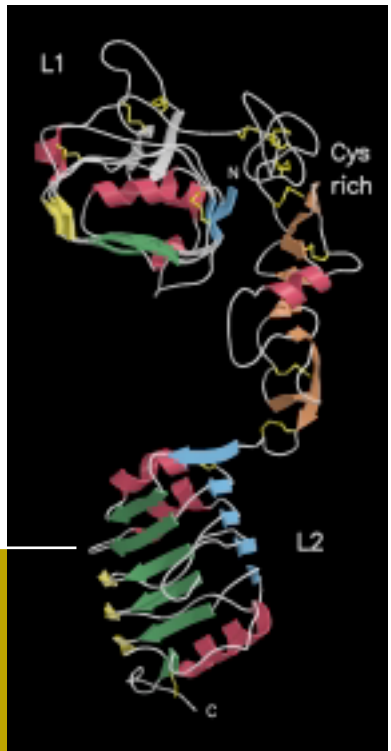
Australia's Opportunity and Challenge

What is Biotechnology?

Biotechnology is a broad term for a group of technologies based on the application of biological processes. It has diverse applications in medicine, agriculture, food processing, manufacturing and environmental management. The term "modern biotechnology" is used to distinguish recent, research based activities from traditional fermentation technologies such as bread, cheese or beer making, and animal and plant breeding, which were the first examples of biotechnology. Modern biotechnology includes a range of techniques from recombinant DNA technology, molecular and cellular biology, biochemistry and immunology through to information technology. Gene technology is a specific subset of biotechnology, based on the manipulation and modification ("recombination") of the genetic material of living organisms to develop new characteristics, processes and products.

Biotechnology is a powerful enabling technology, with applications that have the potential to revolutionise many industry sectors including agriculture, forestry, fishing, pharmaceuticals and health, chemicals, textiles, food processing, environmental industries, energy and mining.

Biotechnology is already responsible for a growing range of new and better treatments for common diseases. There are more than 350 biotechnology drug products and vaccines currently in human clinical trials, more than a hundred products already on the market and hundreds more in early development in the United States alone. These medicines are designed to treat various cancers, Alzheimer's disease, heart disease, diabetes, multiple sclerosis, AIDS, obesity and other conditions.



There are now more than 100 biotechnology-based pharmaceutical products on the market and 350 in development.

Biotechnology derived pregnancy kits are assisting in early and simple detection.

Biotechnology is responsible for hundreds of medical diagnostic tests that detect diseases earlier, thereby ensuring more successful treatment, and that keep the blood supply safe from viruses. Home pregnancy tests are also biotechnology diagnostic products. In the foreseeable future biotechnology promises to enable the prediction and early prevention of many diseases, developments that will radically reshape the health industry.

International Pace of Change in Biotechnology

Biotechnology development around the world is moving fast.

It is less than 20 years since the launch of the world's first biotechnology medicine, an insulin product, in 1982. In 1998 Australian farmers first used cotton plants which had been genetically modified to be pest resistant, which has enabled them to reduce their use of pesticides. While biotechnology will continue to be dependent on lengthy research and development efforts, we are now on the threshold of a major expansion in the number and commercial value of applications.

In 1999, total biotechnology revenues in the United States increased by 16% to $US18.6 billion. The 1283 biotechnology companies in the US spent $US9.9 billion on R&D in 1999 and increased employment by 9% to 153,000. Europe and Canada have experienced equally impressive ongoing growth and major Japanese companies have invested heavily in biotechnology for the food and pharmaceutical industries.

Why Biotechnology is Important to Australia

Australia's industrial competitiveness, and hence our standard of living, will be strongly influenced by whether we can grasp the opportunities presented by biotechnology, and underpinned by the knowledge and skills of our researchers. Biotechnology promises to be the next great wave of technological change, bringing changes as radical and pervasive as those wrought by the IT revolution.

Australia is at the forefront of these developments. We have an excellent institutional base, and a number of innovative small companies which, given the right circumstances, could lead the growth of the new industries.

Government invests over $250m per year in biotechnology R&D.

An environment that encourages responsible biotechnology development, and fosters investment in infrastructure, R&D and commercialisation will drive economic growth and maximise Australia's opportunities to be a producer and exporter of key technologies.

Australia's Biotechnology Assets

Australia has substantial research infrastructure in the universities, the CSIRO, Co-operative Research Centres and Commonwealth and State funded research and development organisations. Commonwealth expenditure on biotechnology research and development is in excess of $250 million per year through a range of programs, with private sector spending of a similar order.

Australia has a robust and internationally compatible intellectual property protection system. This is particularly important in an area where research and development are expensive, require long lead times and products are focussed on global markets.

Australia has a sound regulatory framework on which to base its management of the risks and ethical issues associated with genetic research.

The Australian biotechnology sector has registered some significant successes in recent years that are contributing to industry and investor confidence. Most of the more than 130 core biotechnology companies in Australia are small, with high levels of research and development spending.

There has been an increase in the supply of venture capital in recent years, encouraged in part by government policy; but the demand for capital is growing even more strongly. Changes to the Capital Gains Tax provisions are expected to significantly improve the availability of venture capital in Australia.

Most of the major multinational pharmaceutical and agribusiness firms are active in Australia, and have research collaborations with local firms and research organisations.

Challenges for Australian Biotechnology

Australia has a strong foundation for developing and applying biotechnology. We have a very real opportunity to be a significant participant in this dynamic global industry - an opportunity to capture health and environmental benefits, to develop new enterprises, new industries, new bases for competitiveness in existing industries and new international collaborative relationships.

In some sectors, for example agriculture and mining, Australia enjoys significant comparative advantage. However our comparative advantage in such areas may face serious challenge if we do not capitalise on the innovations offered through biotechnology. In others sectors where we do not currently enjoy particular advantages - such as pharmaceuticals, health and environmental industries - biotechnology offers substantial opportunities to improve our competitive position. The challenge will be to seize these opportunities.

Australian firms often lack the financial depth and the management and market expertise to take a product from invention to market; much biotechnology intellectual property is licensed to overseas companies. Such partnerships can be valuable and will continue to be important. But we are not always capturing the maximum commercial and community benefits arising from our research. Australia faces a challenge to extract more value from its intellectual property and investment in R&D.

Genetic research and its application also open significant ethical and consumer issues and there are potential risks to the environment which need to be managed. The Australian community needs to be engaged in an informed debate on the ethical and regulatory issues. A challenge for Australian biotechnology will be to work with the community and earn its confidence as consumers and investors.

Development of the National Biotechnology Strategy

Australian investment in modern biotechnology began in the 1980s and broadened in the 1990s. Biotechnology is now a significant element of Commonwealth research, training, innovation, regulatory and business support programs. These programs, along with examples of the activities they support, are outlined in the publication: *Australian Biotechnology: Progress and Achievements*.

In 1999 the Government established Biotechnology Australia and the Commonwealth Biotechnology Ministerial Council to coordinate government biotechnology activity and to develop a national biotechnology strategy. The Government also

established the Biotechnology Consultative Group (BIOCOG), a panel of experts from industry and the scientific and research community, to provide independent advice to government.

The strategy, which builds on the current substantial Commonwealth support for biotechnology, seeks to:

- Capitalise on our existing advantages in biotechnology.
- Achieve sustainable growth for established and new industry sectors.
- Strengthen coordination among Commonwealth Government activities and partnerships with State Governments.
- Build on industry commitment and active participation.
- Develop a catalytic role for government.
- Provide a basis for ongoing consultation and strategy development.

In developing the National Biotechnology Strategy the views of stakeholders were sought through an extensive consultation process. A Discussion Paper *"Developing Australia's Biotechnology Future"* was published in September 1999, submissions were invited and forums were held in all capital cities. Considerable input was received from a wide range of organisations and from many individuals. BIOCOG and representatives of the States and Territories provided additional advice and consultation on development of the National Biotechnology Strategy. Members of BIOCOG also provided valuable input, along with industry experts, on issues such as the commercialisation of public sector research. In addition, a range of background studies were carried out by Biotechnology Australia or commissioned from independent consultants.

In the area of regulation of biotechnology, effective community consultation was achieved by the Interim Office of the Gene Technology Regulator (IOGTR) gathering community input into draft legislation and related matters.

The National Biotechnology Strategy addresses the six key themes that emerged from consultations and assessments:

- Biotechnology in the Community,
- Ensuring Effective Regulation,
- Biotechnology in the Economy,
- Australian Biotechnology in the Global Market,
- Resources for Biotechnology, and
- Maintaining Momentum and Coordination.

Biotechnology in the Community

Overall objectives

- Increase the public's general awareness of biotechnology and its applications, and of the regulations that safeguard people and the environment in order to enable informed debate and decisions.
- Address ethical concerns relating to biotechnology research and to its potential applications.
- Address the concerns of rural and regional Australia about agricultural and food biotechnology, including potential socio-economic effects of biotechnology, and manage any adverse impacts.
- Pursue the economic and community benefits of improved health through biotechnology.
- Ensure recognition of the capacity of biotechnology research to address sustainability and natural resource management issues.

Raising Public Awareness and Informing a Community Dialogue

Objective

Increase the public's general awareness of biotechnology and its applications, and of the regulations that safeguard people and the environment in order to facilitate informed debate and decisions.

Consumers are seeking balanced information on biotechnology ranging from the basics of gene technology to details of the regulatory processes. The issue of genetically modified food appears to be a particular concern. There is a strong preference from the community for the Government to be the primary source of information on gene technology. In order that there is public confidence in biotechnology, it is essential that the community continue to contribute to the development of Government policy.

Strategies

- Engage the community in discussion of regulatory processes, including testing and labelling of GM foods, and assessing and managing risks to human health and the environment.
- Build community confidence in biotechnology, its regulation, the industry, and the way risks are assessed and managed.
- Inform consumer discussions and listen to community concerns.
- Encourage public contribution to policy decisions.

Biotechnology can improve rural sustainability and competitiveness.

Consideration of Ethical Issues

Objective

Address ethical concerns relating to biotechnology research and to its potential applications.

Modern biotechnology raises significant ethical issues which need to be addressed and openly discussed.

Strategies

- Consult and liaise widely with the community on ethical issues.
- Strengthen and enhance ethical standards and existing approaches to ethical issues.

Impacts of Agriculture and Food Biotechnology on Rural and Regional Australia

Objective

Address the concerns of rural and regional Australia about agricultural and food biotechnology, including potential socio-economic effects of biotechnology, and manage any adverse impacts.

Biotechnology has direct implications for rural and regional Australians including the impact of the technology upon the viability of the family farm, the local community and related businesses. These concerns will require on-going attention as the issues evolve with the technology.

Strategies

- Identify and address relevant issues for rural and regional Australians through continued monitoring and public awareness activities.
- Identify, monitor and assess the opportunities and challenges of biotechnology-related changes in the agriculture and food industries to inform policy responses.

Biotechnology could help control feral animals with enhanced protection of endangered species.

Biotechnology applications have the potential to address agricultural and environmental issues, including salinity.

Pursuing Australia's Health Objectives

Objective

Pursue the economic and community benefits of improved health through biotechnology.

The Australian Health System is having to respond to an ageing population and the associated demands that places on our health budget. Biotechnology can contribute to better health care by improving our knowledge of the basis of health and disease and offering better treatment options in some areas. For example, an early and accurate diagnosis of disease can both improve patient health and lead to significant health savings.

Strategy

- Strengthen Australia's expertise in medical genomics and biotechnology within our existing health and medical research sector.

Sustainability and Public Good Applications of Biotechnology

Objective

Ensure recognition of the capacity of biotechnology research to address sustainability and natural resource management issues.

The capacity of biotechnology to contribute to environmental sustainability, natural resource management, and protection of biodiversity has not been fully recognised. It is important to recognise and publicise the public benefits of much biotechnology research.

Strategy

- Develop indicators to measure the public benefits that biotechnology can deliver in sustainability, natural resource management and biodiversity conservation and publicise these benefits.

Biotechnology research is improving our knowledge of disease and could lead to better treatment.

Ensuring effective regulation

Overall objectives

- Establish a permanent Office of the Gene Technology Regulator (OGTR) and develop associated legislation.
- Institute a system that ensures that potential risks from the introduction of genetically modified organisms (GMOs) are accurately assessed and are managed effectively.

Developing a Rigorous, Efficient and Transparent Regulatory System

Objective

Establish a permanent Office of the Gene Technology Regulator (OGTR) and develop associated legislation.

Currently, there is a range of regulatory agencies which control genetically modified organisms and their products, depending on the end use. Genetically modified foods are controlled by the Australia New Zealand Food Authority (ANZFA), GM medicines by the Therapeutic Goods Administration (TGA), GM agricultural and veterinary chemicals by the National Registration Authority (NRA), GM industrial chemicals by the National Industrial Chemical Notification Assessment Scheme (NICNAS), and border control is managed by the Australian Quarantine and Inspection Service (AQIS) and Australian Customs Service (ACS). There is also an expert advisory committee, the Genetic Manipulation Advisory Committee (GMAC), which provides advice to these agencies and oversees the research and development stage of genetically modified organisms.

As the technology develops, new issues arise that are not covered by other regulatory agencies. For

The Therapeutics Goods Administration (TGA) is one of the partners that regulates genetically modified products and organisms.

Potential risks from introducing genetically modified organisms need to be rigorously assessed and managed.

this reason, the Government has announced that it will establish a permanent Office of the Gene Technology Regulator and associated legislation by January 2001. This Office will replace the advisory system of GMAC and complement the other regulatory agencies. The Office will provide a greater level of transparency and accountability at the research and development stage and will also have a coordinating function to minimise regulatory duplication.

Strategies

- In collaboration with the States and Territories introduce a nationally enforceable system of regulation that safeguards the community and the environment against possible risks, while acknowledging the commercial needs of the biotechnology industry.
- Consult with Commonwealth agencies, State and Territory governments, and a broad range of non-government stakeholders to determine how ethical and socio-economic issues can be incorporated in the regulatory process.

Environmental Risk Assessment

Objective

To institute a system that ensures that potential risks from the introduction of genetically modified organisms (GMOs) are accurately assessed and are managed effectively.

Regulatory decision-making for gene technology should be based on sound scientific risk assessment. Therefore, we must build on the system that ensures that risks in the field have been accurately assessed and are being managed effectively. There is a need to enhance monitoring research on GMOs released into the environment to determine if there are any unforeseen or unintended consequences and to inform the regulatory process.

Strategies

- Establish a framework and a methodology for risk assessment.
- Identify priorities for an environmental risk assessment program.
- In collaboration with CSIRO and other agencies, improve basic knowledge and assess environmental risks associated with genetically modified organisms.
- Monitor and evaluate any impacts.
- Monitor the effectiveness of the regulatory system to ensure that it continues to cover the field.

Biotechnology in the Economy

Overall objectives

- Overcome the critical gap for proof of concept funding and management at the early stage of product and commercial development.
- Establish a critical mass for biotechnology research, commercialisation and application through the development of clusters, incubators and networks.
- Strengthen capabilities for the commercial and strategic management of Intellectual Property in biotechnology.
- Promote the responsible uptake of biotechnology for product and process development in industry.

Addressing the Commercialisation Gap

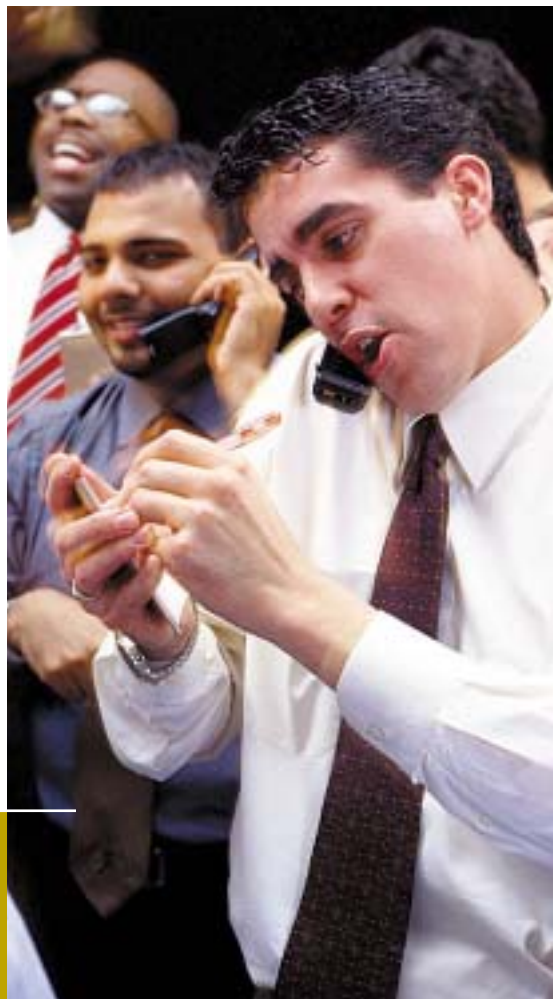
Objective

Overcome the critical gap for proof of concept funding and management at the early stage of product and commercial development.

A major obstacle to the effective commercialisation of Australia's high quality biotechnology R&D is the deficiency in funding at the pre-seed or 'proof-of-concept' stage of product development. Many early stage discoveries are not exploited, or are licensed prematurely, because they lack the funds needed to prove the research concept, identify potential markets and develop a suitable investment proposal. Improving biotechnology commercialisation in Australia will improve the returns on public investment in R&D.

Strategy

- Collaborate with State and Territory Governments and private sector investors to provide proof of concept funds to increase the number of investment-ready proposals for venture capital funds and for programs such as R&D Start.



Increased commercialisation of biotechnology requires earlier access to investment capital.

Biotechnology will improve the international competitiveness of many established industries.

Developing Biotechnology Networks and Clusters

Objective

Establish a critical mass for biotechnology research, commercialisation and application through the development of clusters, incubators and networks.

Biotechnology research and commercialisation are characterised by specialist knowledge and by collaboration between research organisations and industry which helps to achieve the critical mass that is important for major breakthroughs and rapid progress. Internationally these clusters include universities and other research organisations, companies involved in the development and application of biotechnology, companies that provide specialist inputs, and supporting legal, financial and business organisations. It is the presence of these factors that have helped develop strong biotechnology clusters in particular regions of the United States, UK and Germany.

Strategies

- Collaborate with the States and Territories to facilitate the development and national coordination of clusters and networks.
- Strengthen the mechanisms for co-operation between research funders, research providers and industry on biotechnology research and commercialisation

Strengthening Intellectual Property Management

Objective

Strengthen capabilities for the commercial and strategic management of Intellectual Property in biotechnology.

The development of capabilities for the effective management of Intellectual Property (IP) is an important element in securing the benefits of public and private sector research in biotechnology for the Australian community, industry and the environment.

Strategies

- Analyse biotechnology IP management needs of researchers, technology managers and other stakeholders, identify IP management requirements for key export markets, and support development of pilot programs to address these needs.
- Identify impediments caused by R&D lead times and regulatory delays that may affect the effective patent life of biotechnology innovations.
- Promote opportunities for research and industry groups to share experiences in IP management from innovation through to commercialisation.

Applying Biotechnology in Australian Industry

Objective

Promote the responsible uptake of biotechnology for product and process development in industry.

The major economic benefits from a new technology arise from its rapid and widespread diffusion into the broader industrial community. As an enabling technology, biotechnology will have a major impact on the competitiveness of many firms in such established industries as forestry, environmental management, food processing, mining and chemicals.

Strategies

- Encourage access to biotechnology by Australian industries.
- Generate specific biotechnology market sector information.
- Ensure innovative approaches to farm/industry extension for agriculturalists to understand the issues and the strict requirements on the use of the technology.
- Encourage the development and operation of segregated supply chains for food products.
- Undertake technology foresight studies to identify technological and commercial trends and opportunities.
- Promote biotechnology demonstration projects that lead to the integration of modern biotechnology into existing industry.

Australia has a growing number of innovative biotechnology companies.

Australian Biotechnology in the Global Market

Overall objectives

- Attract essential foreign investment and development partners to add commercial value to Australian biotechnology R&D and to develop key overseas markets.
- Develop understanding of the changes in domestic and international markets for genetically modified and non-GM agriculture and food products and improve management of product identification.
- Ensure decisions in international fora do not disadvantage the trading environment for Australian GM agriculture and food products.
- Strengthen Australian collaboration with international biotechnology research centres and programs and build relationships for technology development partnerships.

Biotechnology International Marketing and Investment Promotion

Objective

Attract essential foreign investment and development partners to add commercial value to Australian biotechnology R&D and to develop key overseas markets.

Australian biotechnology development often requires international commercial partners for investment in research commercialisation, product development, regulatory approval and marketing. There is a need to raise international awareness of the growing opportunities in Australia for collaboration and investment in biotechnology R&D and commercialisation within Australia.

Strategies

- Coordinate Invest Australia, Austrade, Biotechnology Australia, State and Territory organisations and industry approaches to international marketing and investment attraction.
- Identify Australian biotechnology trade and investment opportunities.
- Promote Australian biotechnology sector capabilities in key overseas markets.

The Institute of Molecular Bioscience is under construction in Brisbane.

Improving The Assessment of Developments in Food Markets

Objective

Develop understanding of the changes in domestic and international markets for genetically modified and non-GM agriculture and food products and improve management of product identification.

Timely information on the sizes and trends of markets for genetically and non-genetically modified products, and on consumer attitudes underlying the markets, is vital to manage uncertainty. The issues of segregation, preservation of identity and certification of origin go to the heart of any decision to supply markets for both genetically modified and non-genetically modified product. A good understanding of the differentiation of products would enable Australian agriculture and food enterprises to manage and profit from these markets.

Regulatory agencies control the use of genetically modified organisms such as GM soybeans.

Strategies

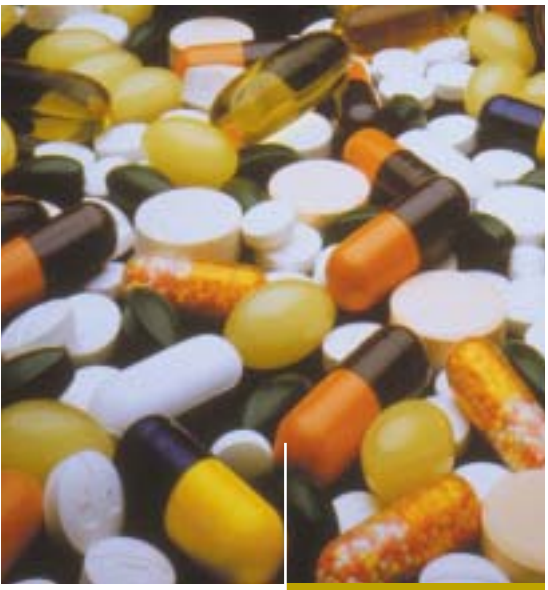
- Establish a cross-industry export market access committee to monitor and report to industry and governments on trends in genetically modified, non-genetically modified and co-mingled markets.
- Facilitate an on-going examination of the costs and benefits of supplying genetically modified product and on establishing identity preservation within Australia's major agriculture and food industries.

Maintaining an Active Role in International Fora

Objective

Ensure decisions in international fora do not disadvantage the trading environment for Australian GM agriculture and food products.

International frameworks that will shape biotechnology patenting, regulation and trade will be determined in ongoing negotiations in a range of international fora including the Organisation of Economic



The pharmaceutical industry is an early adopter of biotechnology innovations.

Cooperation and Development (OECD), the World Intellectual Property Office (WIPO), the World Trade Organisation (WTO) and the United Nations fora. Australia's position in international fora dealing in GM products is that protection of human health and environment safety can be achieved through science-based risk analysis without imposing unjustified barriers to trade in these products.

Strategies

- Continue to pursue a strong presence in regional and multilateral fora to seek recognition and adoption of Australia's position.
- Continue to work bilaterally to ensure access to foreign markets for Australian agriculture and food biotechnology products.
- Report regularly to industry and governments on direction and trade implications for the agriculture and food sector of international negotiations.

International Research Cooperation

Objectives

Strengthen Australian collaboration with international biotechnology research centres and programs and build relationships for technology development partnerships.

Linkages with major international centres of research are vital for the robust development of Australian biotechnology. Building on Australia's strong research capacities provides the opportunity to participate in international research programs - for example, the EU Fifth Framework Program - and to strengthen relationships with neighbours in the Asia-Pacific region.

Strategies

- Facilitate and support Australian participation in international projects in key areas such as bioinformatics, proteomics and through access to major research facilities.
- Develop biotechnology collaboration within existing bilateral research programs.

Resources for Biotechnology

Overall objectives

- Enhance management skills in the biotechnology sector, attract high quality researchers and experienced leaders, encourage entrepreneurship, and monitor demand and supply for specialist skills.
- Facilitate greater cooperation among major research funders and performers to identify the scope for joint funding and collaborative conduct of biotechnology research and infrastructure development.
- Encourage biotechnology research and development that contribute to developing internationally competitive and environmentally sustainable agriculture and food sectors.
- Develop measures to enhance access to Australian biological resources

Human Resources for Biotechnology Development

Objective

Enhance management skills in the biotechnology sector, attract high quality researchers and experienced leaders, encourage entrepreneurship, and monitor demand and supply for specialist skills.

Australia is a small country with high quality but limited resources in the rapidly developing area of biotechnology research and commercialisation. Strong management and entrepreneurial capacity, and availability of required specialist skills, are vital for success.

Strategies

- Improve management of research, intellectual property, and technology within established firms and new enterprises.
- Develop, attract, motivate and retain high quality researchers, particularly in those fields where Australia has strong capacities to commercialise research outcomes.
- Maximise technological awareness and capabilities throughout industries that will be developing and applying biotechnology.
- Develop programs and systems to foster entrepreneurship.
- Monitor emerging skills needs in the biotechnology sector and develop appropriate responses.

Gene technology researchers have developed cotton that is resistant to *Heliothis*.

National Biotechnology Research Cooperation

Objective

Facilitate greater cooperation among research funders and performers to assess and support biotechnology research.

High quality research is critical to Australian competitiveness in the biotechnology sector. While Australia is a strong performer in biotechnology research, and in the basic research underpinning it, the country's research base remains small. We must actively seek opportunities to enhance research performance including through greater cooperation and collaboration.

Strategy

- Facilitate greater cooperation among major research funders and performers to identify scope for joint funding and collaborative conduct of biotechnology research and infrastructure development.

Research for Competitive and Sustainable Agriculture Production and Food Processing

Objective

Encourage biotechnology research and development that contribute to developing internationally competitive and environmentally sustainable agriculture and food sectors.

Australian industry faces challenges in adapting biotechnology research from other countries into its agricultural and food products for a number of reasons. These include ecosystem incompatibility and the occasional reluctance of foreign firms to incorporate their biotechnology into locally adapted conventional material. Local research on biotechnology developments that are suitable for adaptation to our environment would assist Australia to maximise economic and environmental benefits.

Strategy

- Encourage continuing research leading to the introduction of biotechnology into agriculture and food production and processing systems, particularly through the rural Research and Development Corporations.

Management and entrepreneurial skills can enhance Australia's strong research base.

Matters involving access to biological resources are important issues for Australia.

Access to Biological and Genetic Resources

Objective

The development of measures to enhance access to Australian biological resources.

Future development of Australia's interests in biotechnology, particularly in the environmental management, pharmaceutical, forestry, fisheries, aquaculture and agriculture sectors, will be facilitated by clear and transparent terms of access and conditions for the use of Australia's marine and terrestrial biological resources.

Strategies

- Resolve legal issues on the ownership of Australian biological resources.
- Work with sectoral interests to identify their resource needs in biotechnology, including in the utilisation of Australian indigenous and exotic biological resources.
- Work with the States and Territories to achieve nationally consistent regimes on access.
- Develop appropriate documentation, management and access protocols.
- Address matters involving indigenous people and their ownership of biological resources.
- Address issues of access to biological resources within Commonwealth areas, including through regulations under the *Environment Protection and Biodiversity Conservation Act 1999*.

Maintaining Momentum and Coordination

Biotechnology Australia and Australian Biotechnology Advisory Council

Objective

Support the ongoing coordination and review of Commonwealth biotechnology policy and programs and support the work of the Biotechnology Advisory Council.

Biotechnology Australia, along with its five member departments, will have the key role in implementing and evaluating the National Biotechnology Strategy and in coordinating and managing the government's non-regulatory biotechnology activities.

Strategies

- Establish a high level Biotechnology Advisory Council to advise on non-regulatory biotechnology issues - including research and development, international links, commercial developments, public interest issues and ethical issues.
- Coordinate Commonwealth biotechnology-related policies and activities, and maintain cooperation between the Commonwealth and the States and Territories.
- Support the ongoing evaluation and development of the National Biotechnology Strategy, including through benchmarking Australian biotechnology development with international performance.

The molecule responsible for protecting coral from the sun is being used to develop sunscreen products for humans.

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Page 8: CSIRO Health Sciences and Nutrition

Page 13: Agriculture, Fisheries and Forestry — Australia

Page 14: Clive Marks, Victorian Institute of Animal Science

Page 15: (top right): CSIRO Mathematical and Information Sciences; (lower left): University of Queensland

Page 16: Therapeutic Goods Administration

Page 17: Biota Holdings Ltd

Page 19: CRC for Bioproducts

Page 20: CSL Ltd

Page 21: University of Queensland

Page 22: Tyson Sadlo Photography

Page 25: CSIRO Plant Industry

Page 26: SG Szabo

Page 27: Australian Institute of Marine Science

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