NEW ZEALAND BIOTECHNOLOGY STRATEGY

a foundation for development with care

NEW ZEALAND BIOTECHNOLOGY STRATEGY

Ministerial Foreword

On behalf of my Cabinet colleagues, I am pleased to present the New Zealand Biotechnology Strategy, which outlines the Government's vision and direction for the development of biotechnology in New Zealand.

Biotechnology is an industry in itself, but it is much more than that; it is a sector generating biological knowledge, skills and technology that can contribute in numerous ways to achieving our economic, social and environmental aspirations.

The Royal Commission on Genetic Modification pointed to the 21st century as "the biotechnology century" and recommended that New Zealand develop a biotechnology strategy. The Growth and Innovation Framework, launched by the Prime Minister in February 2002, also recognises the importance of biotechnology to New Zealand's future. We want New Zealanders to participate in and benefit from the development and innovation of this fast-moving technology sector.

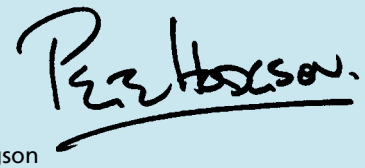
New Zealand is in a fortunate position. Our economy is built on an outstanding ability to add value to natural resources by applying biological knowledge. We have world-class strengths in agriculture, forestry, animal and human health research, and forensic and environmental research, all of which involve biotechnology. Emerging applications have the potential to transform many industries, using biological processes to enhance the quality of life. Examples include improved diagnostics for human and animal health, pest control, industrial processes with reduced waste streams and the development of biodegradable products.

We want to gain these benefits in a responsible way. The Royal Commission on Genetic Modification emphasised "preserving opportunities" and "going forward with care". No one pretends that wrestling with opportunities and challenges in a fast-moving and complex area is easy, but standing still is not an option.

This strategy is about development with care. Care comes from recognition that the biotechnology sector will be strengthened by engagement with society, by building understanding on both sides of diverse perspectives, and by having regard for ethical and cultural concerns. Care is also provided by robust regulation that safeguards people and the environment.

The Biotechnology Sector Taskforce, set up under the Growth and Innovation Framework, has highlighted important factors for commercial growth of New Zealand biotechnology. A growing biotechnology sector depends on a deep and sophisticated knowledge, skill and research base; investment and infrastructure that are based on our strengths and directed at commercialisation; and strong links between research and industry in New Zealand and abroad to promote the uptake of biotechnology.

At the core of the strategy is an ongoing commitment by the Government to work with people in communities, researchers and industry, so New Zealanders together can achieve benefit from developing and applying our world-class biological knowledge, skills and innovation.



Pete Hodgson
Minister of Research, Science and Technology
May 2003

What is Biotechnology?

In a sense biotechnology has been with us for centuries. Broadly defined, biotechnology is a term for a group of technologies that are based on applying biological processes to solve problems and make products. Nature itself is not static and humans have always built on and enhanced biological processes. Traditional biotechnologies include fermentation applications such as beer, cheese, bread making and cosmetics, as well as animal and plant breeding techniques.

It is the opportunities and challenges associated with the development and application of modern biotechnology that are the main focus of this strategy.

The term 'modern biotechnology' is used to describe recent research and applications that relate to molecular and cellular biology. It includes a range of techniques from microbiology and biochemistry through to gene technology.

Some people mistakenly think that biotechnology and genetic engineering (GE) are the same thing. In fact GE, based on the modification of genetic material, is only one aspect of gene technology, which is itself a specific subset of modern biotechnology. Examples of modern biotechnology and its uses in New Zealand are outlined throughout this strategy.


LIVESTOCK


HORTICULTURE

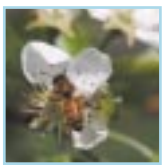

DAIRY


FORESTRY


MARINE


WINE


MEDICINE


NATURAL PRODUCTS


THE ENVIRONMENT

Vision, Goals and Policy Principles

A Vision for Biotechnology in New Zealand

New Zealand responsibly develops and applies our world-class biological knowledge, skills, innovation and technologies to benefit the wealth, health and environment of New Zealanders, now and in the future.

Three goals support the Government vision for biotechnology:

Build understanding about biotechnology and constructive engagement between people in the community and the biotechnology sector.

Grow New Zealand's biotechnology sector to enhance economic and community benefits.

Manage the development and introduction of new biotechnologies with a regulatory system that provides robust safeguards and allows innovation.

Guiding Principles

Government biotechnology policy will be guided by a commitment to:

Benefit for New Zealand – Focus on outcomes from biotechnology that benefit the wealth, health and environment of New Zealanders.

Sustainable development – Meet present needs without compromising future generations, through integrating economic growth, social equity and environmental and cultural well-being.

Responsibility and ethics – Responsible, ethical use and uptake of biotechnology, in a way that safeguards the well-being of both people and the environment, by effective identification and management of risks and uncertainty.

Innovation – Foster and encourage innovative biotechnology developments.

Partnership and participation – Work in partnership with the sector and involve citizens in public policy and ethical issues, through open information and participation processes that acknowledge diverse community interests.

Treaty of Waitangi – Work in partnership with appropriate Maori authorities to empower Maori in development decisions that affect them and enable Maori to participate so as benefit their economic, social and cultural well-being.

Biosecurity and biological diversity – Maintain biosecurity and protect biological diversity, particularly that of New Zealand's unique flora and fauna.

Why we need a Government strategy for biotechnology

The Royal Commission on Genetic Modification (RCGM) recommended New Zealand develop a biotechnology strategy "to ensure that New Zealand kept abreast of developments in biotechnology, and that these were used to national advantage while preserving essential social, cultural and environmental values". Subsequently, the Government, in its Growth and Innovation Framework (GIF), has identified biotechnology as one of three enabling sectors critical to New Zealand's future, with wide applications across the economy. (The other two sectors are information and communications technology and creative industries.) A Biotechnology Sector Taskforce was set up as part of the GIF work to specifically focus on the commercial growth of the sector.

Biological knowledge already earns income for the country through farming, horticulture, fishing, forestry, industrial processes and ecotourism. It also plays a leading role in keeping our environment and people healthy. Modern biotechnology provides opportunities for New Zealand to build on our strong biological base. The Government believes we need to focus on fostering the development and uptake of this enabling technology so it can add value in a wide range of our industries, through improving productivity and generating new products and services.

New Zealand has the makings of a world-class centre for biotechnology research. The Government believes we must move to ensure we are equally smart about using this research to derive benefits for New Zealand, as well as the rest of the world.

All emerging technologies throw up challenges, and modern biotechnology throws up more than most. The complexity of some of the science can be challenging. Some of the science and potential applications challenge our understanding of what it is to be human. There is a need to establish clear values about our responsibilities to wider society and the environment. We also need to come to grips with effective ways of managing risks and uncertainty.

Generating value from biotechnology is also challenging. The commercialisation path from discovery to tried and tested products, particularly for bio-pharmaceuticals, can be longer and more prone to failure than most other areas of technology. Other countries have benefits of scale and resources to push their advantage with biotechnology.

These challenges are not a reason for standing still or saying "it is all too hard". They are a reason for putting in place processes and initiatives that will enable us to tackle the challenges as we move forward.

This Biotechnology Strategy provides an integrated approach to addressing the opportunities and challenges presented by this rapidly evolving technology - for realising benefits in a responsible way.

Key themes from consultation

The strategy links key themes that have emerged from extensive consultation and public dialogue. The discussion has been conducted in many forums, including feedback on the strategy discussion document released in October 2002, deliberations of the Biotechnology Sector Taskforce and the earlier consultations of the RCGM and the former Independent Biotechnology Advisory Council (IBAC).

The themes are:

- **leadership and co-ordination**

  There is a need for greater long-term certainty about the environment for biotechnology in New Zealand. A clear commitment to development and assurance is seen as important. There was a call for stronger co-ordination and clearer leadership, both within the sector and across government, to support the integrated approach in the strategy framework;

- **fostering community awareness of and engagement in biotechnology**

  There is a need for easily accessible, independent information about new biotechnology developments, and for informed debate and dialogue. A challenge for the New Zealand biotechnology sector will be to work with different groups in the community to discuss and address issues and concerns and thereby earn their confidence as consumers and investors;

- **harnessing New Zealand's biotechnology strengths and the contribution of the sector to our economic, social and environmental well-being**

  A partnership between industry and government is seen as a key to progressing development of the sector for the well-being of the community.

  The sector itself is seen as needing to be more proactive about growing and using our current biotechnology strengths in agriculture, horticulture, forestry and biomedicine; strengthening clusters and networks; increasing the uptake and transfer of research into products and services of value; and promoting New Zealand biotechnology under a national branding approach.

  The Government is seen as a facilitator, building capability and infrastructure, funding fundamental research, encouraging development investment, fostering global linkages and ensuring a workable regulatory regime.

  A linked theme that emerged is the need for decisions on biotechnology development and use to enhance and support other government goals, especially sustainable development, public health priorities and environmental management, including biodiversity and biosecurity.

- **managing risks and having regard for ethical, cultural and innovation dimensions**

  Consultation indicated a growing pragmatism about biotechnology. People recognise that biological knowledge and skills have been a key feature of our economy in the past and will be in the future. While some are opposed to the use of genetically engineered products outside laboratories, many others are open to case-by-case assessment and risk management approaches to new biotechnology.

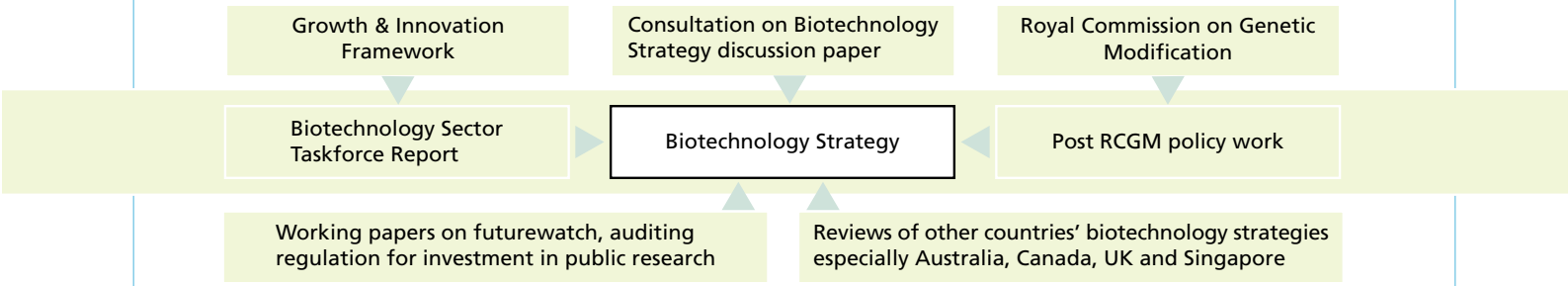
  Trust in a rigorous regulatory system and well signposted opportunities for input into public policy issues, ethical and cultural matters are regarded as important. At the same time it was strongly suggested that regulatory and consultation processes be designed and conducted in ways that do not stifle innovation;

- **fostering Maori participation in biotechnology research and commercial development**

  A recurring theme in the consultation is the importance of Maori participation in biotechnology research and commercial development. Aspects that were highlighted are:

  - Maori have much to offer and much to gain from biotechnology. As tangata whenua they have a major interest in, and deep knowledge of, natural resources and primary sector industries that are strongly connected with biotechnology;
  - the scientific community must take a lead in constructively interacting with Maori at all stages of biotechnology development, with an emphasis on consultation early in the research process;
  - incorporating knowledge of Matauranga Maori and Maori culture is seen as a part of building New Zealand's science capacity;
  - Maori leadership is seen as important in encouraging knowledge of science. In particular there is value seen in building a body of Maori scientists and using them to strengthen science programmes aimed at Maori in schools, and to encourage and provide mentoring for young Maori scientists;
  - recognition of Maori collective approaches to indigenous knowledge and intellectual property and resolution of the WAI 262 claim were identified as issues to be addressed.

This strategy statement is also complemented by a wide range of background and supporting material, as indicated below. Much of this material can be accessed via the Ministry of Research, Science and Technology web page; www.morst.govt.nz.



Case Study

Maurice Wilkins – third man of DNA

The story of the DNA double helix has become part of our scientific folklore – and New Zealander Maurice Wilkins was a key figure in those exciting times.

Maurice Wilkins was born in the isolated Wairarapa community of Pongaroa in 1916.

He gained a physics degree from St John's College, Cambridge, in 1938 and soon began work on radar for the war effort. With this expertise he was moved to the Manhattan Project, an American wartime initiative that ultimately saw the deployment of two nuclear bombs. This experience made Maurice Wilkins a vocal opponent of nuclear weapons.

Wilkins instead began working on the application of X-ray crystallography to biology. He devised a method that allowed the long and fragile molecules of DNA to be pulled out parallel to each other, so that the photographs showed their actual shapes. These patterns, taken in collaboration with Rosalind Franklin, alerted James Watson and Francis Crick to the possibility that DNA was helical. After several false starts, this allowed Watson and Crick to build their correct model of the structure of DNA.

Finally, on 25 April 1953, in one of the truly defining moments of 20th century science, three papers juxtaposed in the science journal Nature detailed the structure of DNA. The implications of this discovery were at least as great as those that led to the atomic bomb – but in a far more positive way. In 1962, Wilkins, Watson and Crick received the Nobel Prize in Physiology or Medicine for this discovery.

Now 86, Maurice Wilkins lives in London, where he continues to teach at King's College and is currently completing his biography.

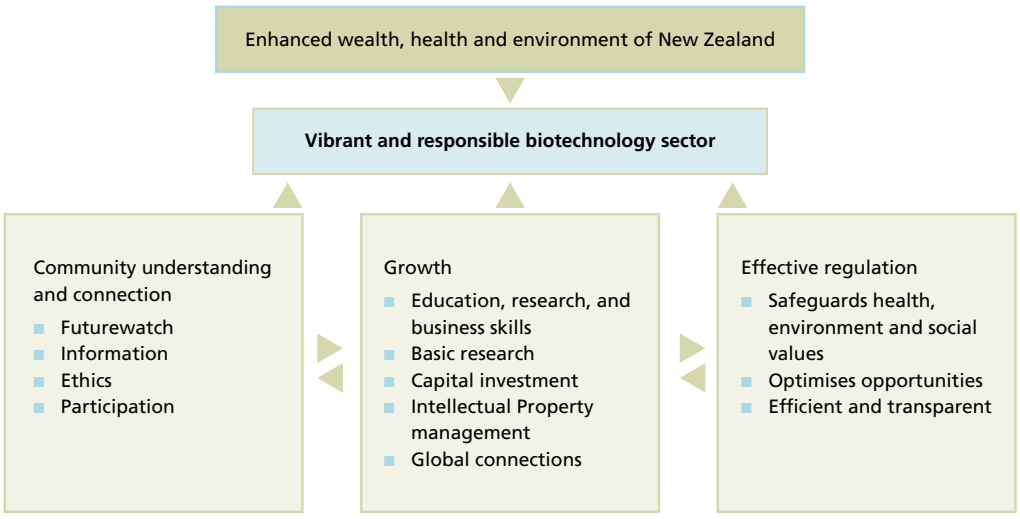
Strategy Approach

This strategy is about development with care. Care comes from recognition that the biotechnology sector will be strengthened by engagement with society, building understanding on both sides of diverse perspectives, and by having regard for ethical and cultural concerns. Care is also provided by robust regulation that safeguards people and the environment.

In a fast-moving and complex area the Biotechnology Strategy is not so much a blueprint as a compass for guiding direction. Achieving development with care requires smart and flexible ways of thinking and working. To develop the biotechnology sector we need to foster our science and research base, build on our strengths and facilitate links that will promote investment and commercial growth. We need to apply biotechnology to add value across a wide range of New Zealand industries. We need to pursue ways it can be applied to contribute to biosecurity, to protect our environment and our unique biodiversity.

The strategy sets out a vision, goals and guiding policy principles for the development and use of biotechnology in New Zealand. Each goal and its associated objectives are supported by a set of key actions. These include actions already underway, and new initiatives set out in the 2003 Budget. In many cases, objectives and actions contribute to more than one goal. Many of the actions pick up themes highlighted in the Biotechnology Sector Taskforce recommendations. Other taskforce recommendations will be considered in the context of the GIF processes.

At the core of the strategy is a commitment to ongoing dialogue between the community, the sector and the Government, so New Zealand can achieve a growing sector that the public trusts. Constructive community engagement and effective regulation are goals that underpin biotechnology growth and development. Achieving community involvement and confidence in regulation should not be regarded as a brake on biotechnology. They are a crucial part of the road ahead if biotechnology is to advance in a sustainable way.



GOAL

Community Engagement

Build understanding about biotechnology and constructive engagement between people in the community and the biotechnology sector.

Biotechnology is a rapidly advancing technology throughout the world. Like information and communication technologies, biotechnology is now providing powerful tools that will become part of our everyday lives. With their power comes the potential to do much good, but also responsibility for their safe and ethical use.

Biotechnology research and development needs to be considered in a broad community context. It must go hand in hand with an informed, inclusive approach to decision making about its uses, and take into account factors beyond those of individual choice. Consumers and other groups in the community must therefore have information and opportunities to be involved.

People will have different needs for information. Some will want to know why a particular technique is useful, others will want to understand how it works, and others will want to know how any risks can be managed through regulatory processes, so they can be part of the discussion over its introduction. For many new biotechnologies, New Zealanders will simply marvel and become early adopters as they have done for other technologies. Some biotechnologies, however, will pose questions of cultural, ethical or spiritual values for some people. They will want to understand, discuss and sometimes challenge or even reject, particular applications on the basis of their values.

Meeting these needs requires a variety of information and other processes. Many of these will be interconnected and iterative. Information helps informed debate and discussion but it does not necessarily resolve ethical and values issues. Broad and diverse perspectives and knowledge need to be brought to bear on decision-making processes and sector development. Researchers and developers must themselves work to build understanding and positive connections with different community groups. The Government also plays an important role in providing access to quality information and opportunities for dialogue and consideration of cultural, ethical and spiritual issues.

Objectives

1. **Improve community access to quality information about biotechnology developments, as well as information on regulatory processes for assessing potential benefits and risks and providing safeguards.**
2. **Strengthen ways to foresee new and emerging biotechnologies (futurewatch) with early identification of potential opportunities and concerns.**
3. **Provide opportunities to consider cultural, ethical and spiritual issues.**
4. **Promote active engagement and dialogue between researchers and developers and different groups in the community, to enable New Zealanders to contribute to biotechnology directions in New Zealand.**

1. Improving access to quality information

Many New Zealanders are keen to understand new biotechnologies. They want information that explains the science and how other countries are using these technologies. They also want information on the risks and benefits, and on the checks and balances that are in place here and overseas. Other people will want information on the sector, who is doing what, New Zealand's areas of strength, research directions, trends and market opportunities.

Information must be easily accessible and easily understood. It must demonstrate a range of perspectives and be from sources that are regarded as independent and trustworthy. The Internet has increased the ability of people the world over to find and collect their own information. Establishing a portal for New Zealand biotechnology information with links to relevant websites could be worthwhile. It will also be necessary to use varied communication styles and media channels including print, TV, video and seminars to ensure material reaches different audiences.

Key Actions

- **Make information available on different aspects of biotechnology (science, research, the market sector, regulation and ethics) through a range of government and non-government sources, using a variety of media.** Sources are numerous and include government agencies, research institutes, the Royal Society of New Zealand (RSNZ), sector bodies such as BIOTENZ and specialist groups. Recent initiatives include the BiosphereNZ website and the Royal Society's DNA50 website. (See Annex Three for a list of websites.) Consideration will also be given to the appropriateness of establishing a New Zealand biotechnology portal website.
- **Support school biotechnology education with resources**. The technology curriculum specifies biotechnology as one of the areas in which students will be expected to carry out activities. The science curriculum strand "Making Sense of Science and its Relationship to Technology" can use exemplars from biotechnology. Support will be given to produce resources to meet these curriculum needs, including addressing ethical issues. Companies will be encouraged to develop programmes that involve students in biotechnology activities, such as Genesis Research and Development's Harakeke project (see page 15).

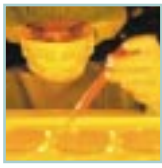
2. Strengthening futurewatch

Futurewatch activities scan, analyse and disseminate information on emerging developments to provide early alerts of new opportunities and issues. Many scanning activities are already in place, especially through research institutions, industry and business organisations and within the health sector, although this activity will not always be particularly focused on biotechnology. There is a need to strengthen futurewatch capacity to enable better and earlier identification of emerging biotechnologies that should be discussed by New Zealanders.

Enhanced biotechnology futurewatch capability, linked to the work of the Bioethics Council, will provide a source of information and analysis that can be linked to processes that involve New Zealanders in decision making on new biotechnologies. It will also improve the Government's capability to respond to new biotechnologies in the New Zealand context, including biotechnologies that link with other technological developments such as nanotechnology.

Key Actions

- **Implement biotechnology futurewatch activities, to be funded through Vote Research, Science and Technology (RS&T).** Futurewatch will scan for emerging biotechnologies and develop early assessments of issues and opportunities. These scans and assessments will feed into the work of the Bioethics Council, policy ministries and other relevant forums.



3. Providing opportunities to consider cultural, ethical and spiritual issues

Toi te Taiao: The Bioethics Council, set up by the Government in response to a recommendation of the RCGM, will play a key role in enhancing New Zealand's understanding of the cultural, ethical and spiritual aspects of biotechnology, and ensuring that biotechnology development has regard for the values held by New Zealanders. Amendments to the Hazardous Substances and New Organisms Act (HSNO) will also strengthen provisions for consideration of cultural, ethical and spiritual matters. Research on social and cultural aspects of biotechnology are also important in fostering understanding of the concerns, values and behaviours that are part of the New Zealand context for biotechnology development and use.

Key Actions

- **Implementation of the Bioethics Council work programme.** The Bioethics Council will provide independent advice to the Government on biotechnological issues that have significant cultural, ethical and spiritual dimensions. It will also provide information and be involved in public dialogue on cultural, ethical and spiritual aspects of biotechnology.
- **Enact amendments to HSNO that support the consideration of cultural, ethical and spiritual matters.** The ministerial call-in powers have been extended to include these matters. As well, amendments to reflect better the Treaty of Waitangi include adding knowledge and experience of the Treaty and tikanga Maori to the knowledge and experience that the Minister for the Environment considers when appointing members of the Environmental Risk Management Authority (ERMA) Board.
- **Support research into areas of socio-economic and ethical aspects of biotechnology.** Over the past two years there has been a significant increase in funding for social research aspects of biotechnology. This includes projects such as "incorporating tangata whenua values into scientific decision-making", "ethical impacts of genetic technologies" and research on community dialogue models.

4. Promoting active engagement and dialogue

For New Zealanders to have trust and confidence in the development of new biotechnologies, they need to be involved in discussion and debate about their introduction. People have expressed a need to be able to have a dialogue with those involved in developing the new biotechnologies.

The aim of dialogue is to develop constructive relationships between scientists and developers in the biotechnology sector and different groups in the community. By having the chance to share information and views, people can gain greater trust and confidence in science and technological development. The science and technology community, in turn, can gain greater trust and confidence in the public's ability to contribute to decisions about science issues. Trust and confidence are not to be measured by the automatic acceptance or rejection of new technologies by society. Dialogue will seek to make science more responsive to its social context, as well as increasing community understanding of the processes and methods of scientific research and development, including provisions for ethics and safety.

Key Actions

- **Support and facilitate dialogue initiatives through instruments such as the Science and Technology Dialogue Fund (in Vote RS&T).** This fund has been set up to pilot new ways of engaging New Zealanders over scientific developments. The effectiveness of these approaches will be evaluated and reported back to the science community.
- **Fund outreach activities.** These activities highlight what is behind key scientific developments, e.g. through Science Centres, Royal Society activities and science outreach organised by community groups through the Science and Technology Promotion Fund.
- **Support the development of Maori initiatives to develop effective communication models and resources that will foster constructive interaction with Maori communities on science and research generally, as well as specifically on biotechnology.** This involves support for initiatives by organisations such as Nga Kaihautu Tikanga Taiao, the Maori Advisory Committee to ERMA and the network of Maori members of Institutional Biological Safety Committees; the Crown Research Institute (CRI) Maori Managers' network; the National Association of Maori Mathematicians, Scientists and Technologists; and iwi-based science and technology groups.
- **Toi te Taiao: The Bioethics Council.** A key aim of the Council is to promote and participate in public dialogue, particularly on cultural, ethical and spiritual aspects of biotechnology.

Case Study

School students learn about biotechnology 'on the job'

A casual visitor to Genesis Research and Development earlier this month would have been forgiven for thinking that many of the white-coated scientists they saw looked as though they should still be in school.

In fact, many of the younger brigade are still at school. They're the second group of high school students to spend a week in the labs at Genesis as the culmination of their involvement in a programme called Harakeke.

Harakeke's mission is to develop a partnership between the growing biotechnology industry in New Zealand and secondary schools to promote science teaching and learning and business growth. It's a wide-ranging programme that involves students practically in many of the biological, commercial, regulatory and legal aspects of biotechnology.

The project is focused on New Zealand flax, or harakeke, and its potential in the biotech industry. It aims to put in place a core teaching programme that combines a natural biological resource and the power of modern biotechnology.

Every Thursday for seven weeks, 14 Year 12 students from Glendowie College have spent an afternoon with Genesis staff learning what it means to work as a scientist in New Zealand.

The students have had sessions on regulatory, cultural, legal, containment, business and practical issues as well as hands-on work in a biotechnology company.

During their week in the lab they have been working alongside Genesis scientists performing the same tasks as the scientists and learning about the technology and science that underpin Genesis' work. This is no simulation. The students are working on real projects and making real scientific discoveries.

GOAL

Growing the Sector

Grow New Zealand's biotechnology sector to enhance economic and community benefits.

A growing biotechnology sector depends on deep and sophisticated knowledge, skills and research; investment and infrastructure that builds on our strengths and recognises the long path to commercialisation; and strong links between research and industry here and abroad to promote the uptake of biotechnology in beneficial ways.

The sector taskforce has set itself 10-year sector growth targets (e.g. a five-fold increase in the number of core biotechnology companies to over 200 from 40) and identified issues for attention in order to achieve these targets. The taskforce sees the sector as having a strong leadership role, with the Government as a facilitating partner. The Government has a key investment role in ensuring science and research capability.

The following set of objectives focuses on areas where the Government has a role to play and includes areas highlighted by the sector taskforce.

Objectives

1. **Strengthen capability - in science education, basic research, enterprise and commercial skills.**
2. **Build critical mass around areas of strength.**
3. **Facilitate investment for commercialising New Zealand biotechnology research.**
4. **Promote the application of biotechnology to add value to New Zealand industries.**
5. **Increase global participation.**
6. **Ensure biotechnology research to address sustainability, biosecurity and protection of biodiversity.**

1. Strengthening capability

To achieve a vibrant world-class biotechnology sector in New Zealand, we must make sure that New Zealand has the underlying capabilities. We need talented scientists, innovative ideas, excellent research and the skills to link people, research ideas and industry.

The needs of a dynamic sector like biotechnology call for high general levels of science, research and commercial skills, as well as specific specialist skills.

Key Actions

The following action areas require ongoing attention:

- **Enhance science and technology education at all levels**

  Lifting general skill levels in science requires a focus on both participation and achievement. Since 1999 the New Zealand school system has introduced a new technology curriculum that is compulsory from Years 1 to 10 and includes biotechnology as an area of focus. Successfully implementing this curriculum is the current challenge, with a need for supporting material, teachers qualified to teach biotechnology and stronger links between the science and technology teachers. The National Certificate of Educational Achievement now makes it possible to study biotechnology through to Year 13, providing a broader pathway to tertiary study. The Government's Tertiary Education Strategy provides a sound framework for supporting this objective in the tertiary sector.

  Enhancing skill levels will involve:

  - lifting participation in science and technology, especially at the senior secondary and tertiary levels;
  - lifting Maori and Pacific participation and achievement in science and technology;
  - professional development and support for science and technology teachers;
  - development of technology curriculum material related to biotechnology;
  - implementing scholarship and fellowship programmes to support post-graduate science and biotechnology research;
  - industry bodies and government agencies working jointly to identify specific capability and skills gaps and work on ways to address those needs.

- **Recruit and retain scientists and science entrepreneurs**

  - Working with industry on an industry-initiated programme of active recruitment and repatriation of science and entrepreneurial talent. This may include tapping into the New Zealand diaspora through programmes such as "World-class New Zealanders", and greater use of scholarships and fellowships.

- **Foster and draw on Maori biological knowledge and innovative capacity**

  Consultation has shown a clear need to foster and use Maori strengths in the areas of natural resources, their beneficial uses and ecological management. Work programmes in this area include:

  - MoRST work on fostering the creative potential of Maori as innovators, researchers and thinkers. This will involve developing RS&T policies targeted towards a stronger emphasis on Maori creative potential while maintaining an appreciation of social justice and Treaty issues;
  - the work of Maori research units at universities and wananga, including the work of Nga Pae o te Maramatanga, The National Institute for Maori Development and Advancement;
  - Ministry of Economic Development (MED) work on the protection of traditional knowledge, innovations and creativity, in relation to intellectual property and bioprospecting policy.

- **Invest in excellent fundamental research**

  Consultation also reinforced the need to maintain a strong base of fundamental research as the foundation for innovation. Excellence in fundamental research has been a strength and hallmark of New Zealand biotechnology and we must ensure this continues to be the case. The Government is a key player here and has in recent years steadily lifted the level of investment in biotechnology research.

  Actions include:

  - implementing the Centres of Research Excellence (CoREs). Over the past two years the Government has initiated significant new operational and capital funding to build critical mass and extend the research programmes in selected areas of research excellence. Four of the seven CoREs are strongly grounded in biotechnology. (See Annex Three for website link to RSNZ and Centres of Research Excellence.)
  - implementing Performance-Based Research Funding to strengthen excellence in tertiary research;
  - building and enhancing the capability of CRIs;
  - funding increases in the Marsden Fund, the New Economy Research Fund (NERF) and the Health Research Council (HRC).

- **Develop commercial skills and experience**

  New Zealand needs to have 'commercially savvy' scientists and 'scientifically savvy' industry managers. This calls for:

  - implementing cross-disciplinary links at tertiary institutions;
  - greater exposure to best international practices, e.g. Industry NZ working with industry to promote best practice, especially in intellectual property management.

2. Building critical mass around areas of strength

New Zealand biotechnology will thrive if it can draw on its areas of existing and emerging strengths and link these with realistic market opportunities. The sector taskforce has identified key areas of strength and depth that will give us particular opportunities. These include large animal and plant-based biotechnologies; bioprocessing technologies and biomanufacturing; innovative foods and nutraceuticals; as well as small but vibrant biomedical groupings in niche areas, especially asthma, diabetes, bone health, neuroscience and cardiovascular disease.

Promoting clustering and collaboration around areas of strength will be important and the taskforce has identified this as a key area of sector leadership. The Government can support building critical mass, particularly through research funding mechanisms that encourage collaboration and focus on excellence in areas of strength.

Key Actions

- **Strengthen strategic approaches to biotechnology research funding.** As the major research funder, the Foundation for Research, Science and Technology (FRST), working with the sector, is increasingly developing strategic approaches to research funding that will build on strengths and enhance critical mass and collaborative links. This approach also must be co-ordinated with biotechnology-related research funding through the Marsden Fund, CoREs and the HRC. International peer review will be an integral part of benchmarking excellence and strategic focus.
- **Co-ordinate planning for major infrastructure investment in capital equipment and platform technologies.** This also requires close co-ordination between research institutions and government funding agencies (FRST, the HRC, the Tertiary Education Commission (TEC), RSNZ, and Industry NZ). Examples of such infrastructure include next-generation Internet links and bioinformatics databases.
- **Support clustering and developing effective collaboration and alliances.** This support is currently provided by Industry NZ, through its Biotechnology Directorate. This will be further enhanced through the newly merging agency, New Zealand Trade and Enterprise (NZTE) combining industry, investment and trade support.

3. Facilitating investment in commercial development

Attracting capital into commercial development of biotechnology is a challenge worldwide. Investment in biotechnology, throughout all its phases from research to manufacture and marketing, is at the higher end of the risk spectrum. The pathway, particularly for bio-pharmaceuticals, is longer, more costly and has more chance of failure than for most other technologies. (For instance, US$800 million is a benchmark figure to take a new drug from discovery to market.)

For New Zealand, our high number of small start-up companies, relatively poorly developed commercial skills, small domestic investor market and distance from global biotechnology and investors heighten this growth challenge. Constraints concerning access to capital can be acute at early stages of development, as businesses seek to develop ideas into new commercial products and processes, and 'prove' the concepts.

Key Actions

- **Provide funding to increase the rate of commercialisation, particularly at the early stages of commercial development,** including:
  - supporting the public funding mechanisms already available to foster commercialisation, including Technology for Business Grants, Grants for Private Sector Research and Development and Industry NZ funding grants; and the New Zealand Venture Investment Fund;
  - implementing a new pre-seed accelerator fund;
  - providing more flexibility in FRST funding of experimental development so projects can be funded up to the pre-seed stage of commercialisation.
- **The Government will also consider the Biotechnology Taskforce recommendation for a private-public funding mechanism, specifically targeted to biotechnology development, with flexibility to span all stages of commercialisation.**

4. Applying biotechnology in New Zealand industries

The application of modern biotechnology research can add value to the products and processes of many New Zealand industries including agriculture, forestry, marine, environmental and pest management, and human and animal healthcare. To gain these benefits and ensure international competitiveness it is important to promote speedy and widespread diffusion of biotechnology into the broader industrial community, while maintaining responsible and sustainable use.

Industry initiative and entrepreneurship are essential. The Government can promote research-industry linkages and facilitate market information including technological and commercial trends and opportunities.

Key Actions

- **Stimulate market-led research,** especially through the development of a best practice programme jointly developed by industry, CRIs and tertiary research providers for achieving effective connections between industry and science.
- **Encourage early collaboration between research providers and businesses,** especially through funding instruments that provide incentives to link. Examples include FRST's Research for Industry funding, Research Consortia and TechNZ funding.
- **Promote the enabling aspects of biotechnology** to a wide range of industry sectors, especially building on the synergies between the biotechnology and the primary sectors. Government agencies, such as the Ministry of Agriculture and Forestry (MAF) and NZTE can facilitate through communicating biotechnology market information and demonstration projects that promote the integration of biotechnology into industries.

Case Studies

Research to prevent asthma

The human body's immune response to tuberculosis micro-organisms could lead to a vaccine to prevent asthma.

Asthma is caused by the inflammation of over-sensitive breathing tubes in the lungs. Research has revealed that an over-active immune system is the underlying cause of the smooth muscle, mucus and nerve changes seen in the lungs of many asthmatics. Evidence has also been found that exposure to some types of infection, including Tb, may actually decrease the prevalence or severity of asthma.

Research by scientists at the Wellington-based Malaghan Institute, working in collaboration with the University of Otago and AgResearch, includes trying to find ways to switch off or block the body's 'Th2' cell immune response in order to alleviate asthma symptoms. Th2 cells, which produce a specific set of hormones that can damage lung tissue, have been identified as a principal culprit in asthma.

Scientists have found that key molecules produced by the Tb vaccine can stimulate a 'protective' infection, and by doing this, block the development of asthma symptoms.

A preliminary clinical trial revealed potential for unwanted reactions, and work is now concentrated on extracting the active ingredients. Other infectious agents are also being screened for their ability to suppress the onset of asthma.

Selling naturally 'good' bugs

Preventing tooth decay by using the human body's naturally occurring 'good' bacteria is being investigated by New Zealand company BLIS Technologies.

Clinical trials, in association with the Otago University Dental School, began in February 2003 with the aim of developing a bacterium-containing product that, when used with brushing, will combat plaque and thus prevent tooth decay.

The company has also lodged a patent for a bacterium to combat ear infections. The bacterium, which appears naturally in the nasal passages of healthy children, has shown promise in preventing ear infections and sinusitis.

Early lab trials show the bacterium inhibits a variety of bugs that lead to ear infections. Used after a course of antibiotics, it could help replenish the body's natural defences. Pilot trials with people suffering chronic ear infections are planned.

BLIS Technologies was formed in June 2000 to build on Otago University work and pursue the commercialisation of "BLIS" - Bacteriocin-Like Inhibitory Substances.

It already has two products on the market - BLIS K12 Throat Guard, containing beneficial bacteria, and BLIS Bio Restore, which restores naturally occurring good intestinal and oral bacteria following antibiotic use.

When antibiotics are taken, the good bacteria necessary for everyday well-being are killed along with undesirable bugs, upsetting the body's natural balance and making people prone to side effects.

Case Studies

Leveraging our biotechnology strengths

Dunedin-based biotech company Ovita is using sheep genome research to help farmers improve the quality and productivity of their stock.

The research is not about changing genes, but understanding them and knowing which ones can be passed on conventionally from one generation to the next or mimicked through new vaccines.

Ovita, a New Zealand Wool Board, Meat New Zealand and AgResearch consortium, has identified a number of genes that regulate fertility, along with proteins that regulate ovulation rate. A key discovery is the 'Inverdale' gene - in female sheep one copy causes twins, two copies make the sheep sterile.

Some markers associated with increased reproduction are ready to be commercialised. Ovita expects that in one to two years it will also have developed additional marker tests to help farmers identify sheep with the genetic capability for premium meat production, as well as a test for lice. In two to three years it expects to have a test to detect Johne's disease early, followed by an improved vaccine and in 10 years a new vaccine, and in three to five years to have developed marker tests for desirable body composition, lamb survival and parasite and facial eczema resistance.

As well as offering potentially tremendous benefits to farming, the research will be commercialised in non-agricultural areas such as human therapeutics and veterinary products.

Nutraceuticals from the sea

The National Institute of Water and Atmospheric Research (NIWA) and Ngai Tahu Seafood are working together to develop 'nutraceuticals', in particular biologically active compounds highly sought after in the cosmetics industry for natural skin care products.

New Zealand has an extremely diverse marine environment that presents huge bioprospecting potential. The NIWA-Ngai Tahu partnership brings together expertise in fisheries and aquaculture, bioactive research and nutraceutical development. The two organisations are aiming to source, screen and extract compounds from the by-products and by-catch of New Zealand's fisheries and aquaculture species.

Ngai Tahu Seafood is taking the lead role in the commercialisation stage, having already identified a range of skin care companies interested in the research. It has identified high-value seafood-based nutraceuticals as an area with commercial potential.

NIWA will screen hundreds of compounds to identify potential activity. The type of compounds sought for skin care products are antioxidants, used in anti-aging creams and moisturisers, and vasodilators, which have a relaxant effect on arterial and smooth muscle.

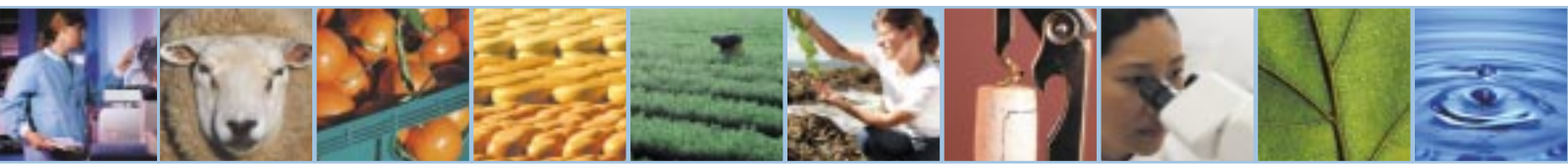
When promising candidates are found the compounds will be purified and the chemical structure determined through further assays and techniques such as nuclear magnet resonance (NMR). It will also be essential to check whether the compounds are unique so the organisations can protect their intellectual property.

5. Increasing global participation

Industry and the Government together can foster international connections that benefit New Zealand. We have much to gain through international links that inform other countries about New Zealand's world-class expertise in biotechnology. We will also gain from collaborating with other countries in ways that offer New Zealand better access to specialist expertise, high-cost research facilities, new technology and investment.

Key Actions

- **Promote New Zealand biotechnology with integrated profiling and national branding.** A start has been made with the BiosphereNZ website set up by Industry NZ and the sector, joint industry-government participation in major international conferences, such as Bio2002 and Bio2003 and showcasing missions in Australia. The Government is committed to further joint international showcasing including hosting high-profile events in New Zealand, such as the APEC innovation showcase.
- **Build focused country and regional links.** Focused country partnerships and regional links can enable greater traction through joint development and showcasing. Industry and government will need to work together to achieve these partnerships in ways that support New Zealand's major trading interests and provide mutual benefit for all partners. Building stronger biotechnology links with Australia is a priority and discussions and exchanges are already underway. The United States of America and East Asian economies, principally Korea and Singapore, are also important partners for scientist-to-scientist links and for the commercial development of biotechnology.
- **Represent New Zealand's interests in and contribute to the multilateral policy arena for the debate and development of international biotechnology protocols.** Themes of interest for international harmonisation include privacy and security, protection of information, food safety, biological diversity, regulation, standards and ethics. Relevant international fora include Asia Pacific Economic Co-operation (APEC), Organisation for Economic Co-operation and Development (OECD), United Nations Educational, Scientific and Cultural Organisation (UNESCO) (bioethics), World Health Organisation (WHO), World Trade Organisation (WTO) and UN Food and Agricultural Organisation (FAO), the Codex Alimentarius Commission, and the World Intellectual Property Organisation.



6. Biotechnology research to address sustainability and biosecurity, and protect biodiversity

The capacity of biotechnology to contribute to environmental sustainability, biosecurity and protection of biodiversity was highlighted during consultation. Examples include reduction of methane emissions from farm animals; control options for major pests, such as possums; cleaner industrial processes; and taxonomic methods to understand and describe our unique flora and fauna. The Government is committed to a proactive approach to funding research and development in these areas.

Key Actions

- **Fund Centres of Research Excellence.** Two of the CoREs; the Allan Wilson Centre for Molecular Ecology and Evolution and the National Centre for Advanced Bio-Protection Technologies are world-class research centres addressing these matters. They have significant government funding to enhance their capacity and extend their research programmes.
- **Fund specific sustainability and bioprotection research projects** – through the FRST 'Sustainablity' research category.
- **Fund biotechnology impacts research** – through the FRST 'Sustainable Biotechnology' portfolio.
- **FRST, in conjunction with the Ministry for the Environment (MfE), the Department of Conservation (DoC), and MAF is to develop a research strategy for environmental biotechnology.**

Case Studies

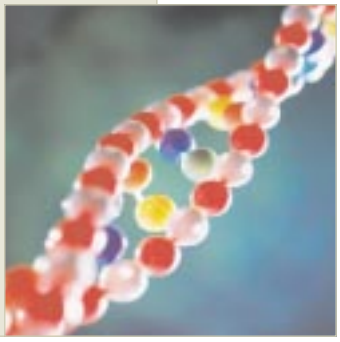
Gene historians learn from the past

A dramatic acceleration in our understanding of the processes underpinning the ecology and evolution of living systems is expected to result from research by the Palmerston North-based Allan Wilson Centre for Molecular Ecology and Evolution.

The Centre, working with Otago, Canterbury, Victoria, Massey and Auckland Universities, is using new tools involving DNA technology and mathematics to study the ecology and evolution of New Zealand plants, animals and micro-organisms.

Recent research, using new techniques such as sequencing of genomes and the study of ancient DNA, has revolutionised our understanding of New Zealand's biodiversity. The concept that New Zealand is a 'Moa's Ark' of relic species, undergoing ancient and slow changes over long periods of time, has been overturned by the information obtained using these techniques.

The research can also provide insights into how New Zealand plants and animals will respond to future environmental changes, such as climate change, based on how they reacted in the past.



The Centre's research programme includes projects on rates and modes of evolution, biodiversity, human settlement of New Zealand, and new ecological and evolutionary models.

Scientists will be aided by Massey University's newly developed supercomputer 'The Helix' - the fastest computer in New Zealand – using applications designed to analyse large amounts of data such as DNA information.

Bio-cleanup of contaminated sites

Scientists at the CRI HortResearch have found a native white-rot fungus that may be able to clean up toxic sawmilling sites.

Until 1988, pentachlorophenol or PCP was used in New Zealand sawmills as a timber preservative. Its use was stopped after PCP was found to be toxic and persistent in the environment, but there are now around 800 former or existing sawmilling sites in New Zealand that need cleaning up.

HortResearch has identified a native white-rot fungus that can significantly degrade PCP into non-toxic compounds, even when the PCP is at moderate concentrations.

The scientists are now looking to refine further the use of this fungus and use it as a commercial product for cleaning up contaminated sites. There are also good prospects for taking this technology overseas.

The research is part of HortResearch's 'bioremediation' work, a branch of biotechnology that uses biological processes to overcome environmental problems. This often involves treating waste or pollutants using micro-organisms, such as bacteria and fungi, which can break down environmentally unfriendly substances.

The potential for trees, particularly poplars and willows, to be used to suck up heavy metals from contaminated environments is also being investigated. Some species are capable of extracting large amounts of cadmium, boron and other metals or metalloids.

GOAL

Regulation that Provides Robust Safeguards and Allows Innovation

Manage the development and introduction of new biotechnologies with a regulatory system that provides robust safeguards and allows innovation.

The design and operation of regulations must achieve robust safeguards for people and the environment while minimising cost and complexity. The regulatory framework is where innovation and opportunity meet society's safety and ethical concerns. The challenge is to ensure an appropriate balance.

The diagram in Annex One summarises the main components of the regulatory system governing the introduction of new bioproducts and biotechnologies. This framework shows the different approval processes and institutions for food, animal, crop and medicinal developments.

Intellectual property law and bioprospecting regulations are important elements of the regulatory framework surrounding biotechnology. Getting intellectual property law and practice right is vital for supporting New Zealand innovation.

Transparency, predictability and best regulatory practice are essential. The ability to maintain an overview of the system as a whole will also be important in assessing how well it is achieving a balance between assurance and innovation.

Objectives

1. **Ensure regulation effectively assesses and manages risks from the introduction of new biotechnologies.**
2. **Complete and implement the reviews of the Patents Act, the Plant Variety Rights Act and bioprospecting regulation.**
3. **Promote greater transparency and best regulatory practice in the sector.**
4. **Maintain an overview of the biotechnology-related regulatory system to ensure effectiveness and efficiency, and provide for assessments of how well it is achieving a balance between assurance and innovation.**

1. Regulation to assess and manage risks from new biotechnologies effectively

Together, the regimes outlined in Annex One provide a comprehensive and stringent system to achieve safety and environmental protection. The system is participatory, and provides structured opportunities for public consultation and submissions.

New Zealand's case-by-case assessment approach is similar to that of a number of jurisdictions, including Canada, Australia, Japan and the European Union, although specific regulatory requirements may differ. A case-by-case assessment process is also consistent with approaches agreed internationally through the Cartagena Protocol on Biosafety.

Concerns about some newly emerging biotechnologies will occasionally prompt particular regulatory scrutiny. Genetically modified organisms (GMOs) have been one such case. Following extensive consultation and deliberation, the RCGM found that the basic regulatory system was sound in relation to GMOs, and that key institutions were sound in carrying out their functions. The Royal Commission proposed amendments requiring specific consideration and controls for the field testing and release of new organisms, including GMOs. The Government, following policy work and consultation on the discussion document "Improving the Operation of HSNO for New Organisms", has announced a set of amendments to HSNO.

Further areas for current regulatory attention are the therapeutic use of organs and tissues and assisted human reproduction technologies. While human reproductive cloning is now a restricted procedure through recent legislative amendments to the Medicines Act, work is underway to legislate for managing therapeutic uses of human organs and tissues, and to implement a regulatory framework for assisted human reproductive technology.

Key Actions

- **Enact and implement the changes to HSNO, including:**
  - streamlining the approval process for laboratory research involving the development or import of low-risk GMOs;
  - addressing some regulatory gaps relating to new technologies and human cells;
  - streamlining the approval process for medicines and veterinary medicines that are or contain new organisms;
  - fast-tracking approvals of medicines and veterinary medicines for use in emergencies;
  - strengthening incentives to comply with HSNO by establishing liability for harm caused by non-complying activities and a civil penalty regime for breaches of HSNO or approvals granted under the Act;
  - extending the ministerial call-in powers to include cultural, spiritual and ethical matters;
  - including provision for ERMA to impose conditions on the release of new organisms – a new conditional release category;
  - extending the existing regulation-making powers relating to the impacts of hazardous substances, to also cover conditionally released new organisms;
  - establishing MAF as the primary enforcement agency for conditional release, new organisms in containment and unauthorised releases of new organisms;
  - clarifying ERMA's responsibilities regarding the protection of releasing confidential information that is included with an application to ERMA;
  - removing the requirement for contained fermentations of more than 10 litres of new organisms to be considered as field tests and instead to be considered as a development;
  - measures to more appropriately reflect the Treaty of Waitangi relationship in the administration of the Act.
- Enact the Human Assisted Reproduction Technology Bill - to regulate the use of human reproductive technology. The Bill establishes a three-tier framework for ethical decision making consisting of:
  - prohibitions on fundamentally unacceptable practices, such as reproductive cloning;
  - a Ministerial Advisory Committee which will be established to provide advice and develop guidelines for those operating in this area;
  - mandatory ethical approval for non-established procedures, such as newly developed techniques to aid fertility, and for all research.
- Update the Human Tissue Act in light of new social and technological developments in relation to the use of human cells and tissues.
- Implement biotechnology futurewatch activity to help early identification of and work on potential regulatory issues from emerging biotechnologies.

2. Completing and implementing reviews of the Patents Act, the Plant Variety Rights Act and bioprospecting regulation

Intellectual property protection and management are significant elements in improving the pathway from innovation to making new products and services commercially available. This in turn will encourage the generation of economic value. As with other regulatory regimes there is a need for balance; to set the need for individual incentives and a fair return for innovation and development investment alongside other collective objectives, such as early, low-cost public access to generic pharmaceuticals or genetic testing techniques.

The Government is committed to updating the Patents Act and Plant Variety Rights Act to take new social and technological developments into account. Submissions on a discussion document were extended to consider the issue of patent extensions. The Government will pursue introducing amendments arising from these reviews during the 2003 parliamentary term.

Bioprospecting is the examination of biological resources for features that may be of value for commercial development. While bioprospecting in New Zealand is in its infancy it has the potential to create a wide range of benefits for New Zealand. The Government is examining policy options for formulating a framework to manage access to biological resources for bioprospecting. This framework will include a policy for benefit sharing, including recognising Maori interests in relation to biological resources.

Key Actions

- Pursue introducing amendments arising from the reviews of the Patent and Plant Variety Rights Acts, during the 2003 parliamentary term.
- Complete, by December 2003, the review of New Zealand's regulation of bioprospecting activities to establish an overarching policy framework.

3. Promoting greater transparency and best regulatory practice

To support the regulatory design there is a need to promote greater transparency and best operational practice in the sector for safety and ethical approvals, including best ways to work in partnership with Maori authorities and take account of the Treaty of Waitangi. Firms and research organisations also need to develop sound intellectual property management practices, understanding what, when and how to protect new ideas. Best regulatory practice can contribute considerably to minimising costs and complexity.

Sector bodies such as Biotenz, and government agencies including ERMA, Industry NZ and the HRC, can jointly play a key role in fostering and spreading best practice.

Key Actions

- **Hold best regulatory practice workshops** – led by sector groups and supported by government agencies.
- **Provide targeted industry advice on biotechnology-related legislation** – to be led by relevant government agencies working jointly with the sector.
- **Develop an Intellectual Property Management Manual specifically for biotechnology** – to be led by NZTE working jointly with the sector.

4. Oversight of the regulatory system to ensure effectiveness and efficiency

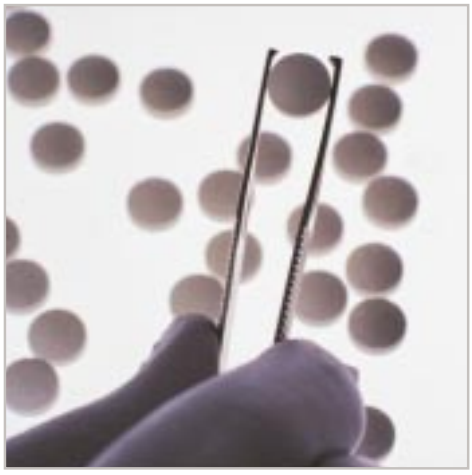
The diagram in Annex One summarises the different approval processes and institutions for food, animal, crop and medicinal bioproducts and biotechnologies. While, as the sector taskforce has noted, it is in our trading interests to keep a gold standard for safety, we must do so in a way that supports innovation and does not load the system with unnecessary complexity and costs.

A number of agencies, such as MfE, the Ministry of Health (MoH), the New Zealand Food Safety Authority (NZFSA) and MAF have regulatory oversight of specific elements of the system. There is, however, a need to assign responsibility for oversight of the system as a whole, to consider the multiple and dynamic links, and particularly the interactions between regulation and innovation. This is not easy, but other countries, notably Canada, are starting to do it, especially with regulations related to key platform technologies.

In line with MoRST's whole-of-government co-ordination role for biotechnology, it is appropriate to assign overview to MoRST, in liaison with other key agencies and industry. As part of this overview activity, the Government has made provision for the conduct of periodic independently contracted system audits to assess whether the regulatory regime and its operation are achieving an appropriate balance between assurance and innovation.

Key Actions

- Assign MoRST an overview role in relation to biotechnology-related regulation, in liaison with key agencies and sector bodies.
- Conduct periodic independently contracted system audits to assess whether the regulatory regime and its operation are achieving an appropriate balance between assurance and innovation.



Keeping the Strategy Fresh - Leadership and Co-ordination

The dynamic, multi-layered and long-term nature of biotechnology development requires a commitment to support the strategy with co-ordinated information and action, regular communication and monitoring. Clear government leadership will be central to the ongoing balancing of development and assurance policy considerations.

It is crucial that the 'development with care' perspective informs the work of the wide range of government ministries and Crown and government-funded agencies with responsibilities and interests in biotechnology in New Zealand. Among the key agencies are those which:

- support the science, research and skill base at the core of biotechnology, including MoRST; FRST; the HRC; RSNZ; the Ministry of Education and increasingly the TEC;
- facilitate industry development and trade and investment activity around biotechnology, including the Biotechnology Directorate in the newly integrated Trade and Enterprise agency and the Ministry of Foreign Affairs and Trade;
- oversee policy regulation and ethical standards relevant to biotechnology, including MfE, which is also responsible for supporting Toi te Taiao: The Bioethics Council; MoH, MAF, MoRST, and DOC;
- increase public awareness and provide information about biotechnology (MoRST, MfE, RSNZ and NZTE);
- oversee policy of the key linked 'growth and innovation' and 'sustainable development' frameworks, including MED, the Department of Prime Minister and Cabinet and the Treasury.

There are also other Crown agencies and advisory bodies with biotechnology-related work programmes and responsibilities. These include regulatory bodies such as ERMA and Food Standards Australia New Zealand (FSANZ), ethical bodies such as the Health Research Council Ethics Committee (HRCEC), CRIs and tertiary research providers.

No one agency can hold all responsibilities, so co-ordination and joint responsibility for implementing a common framework through policy and operational activities are essential.

Government leadership will be provided through key Ministers who will oversee and support a balanced and integrated approach to biotechnology in New Zealand. The Ministers will be convened by the Minister of Research, Science and Technology and will include the Minister of Economic Development, the Minister for the Environment, the Minister of Health, the Minister of Agriculture and Forestry and the Minister of Finance.

The Biotechnology Sector Taskforce has confirmed the need to strengthen and consolidate industry association efforts in one body. It is also planned that the sector taskforce reconvene periodically to monitor and review progress against the taskforce growth targets.

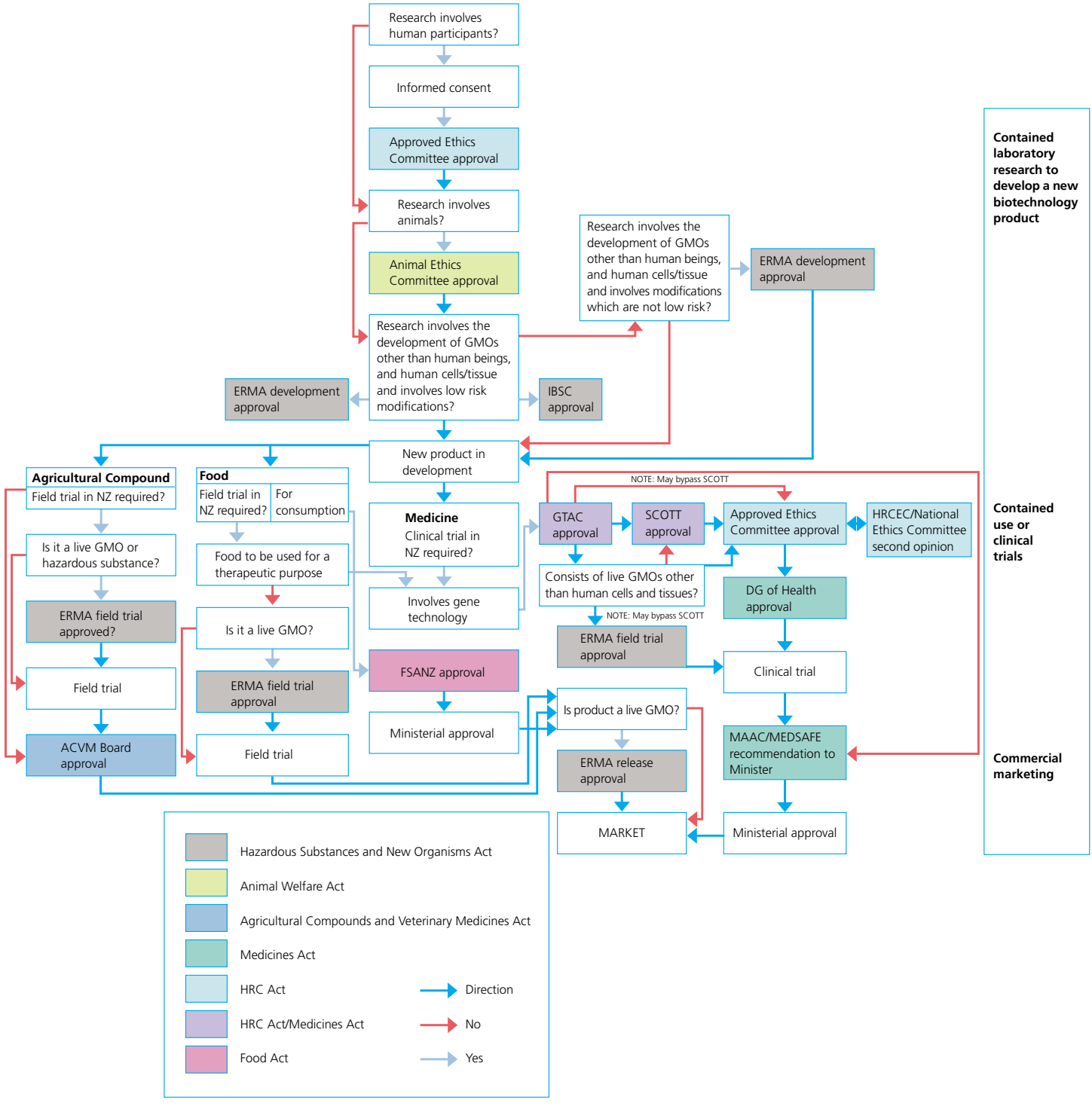
Meeting Expectations – What Will Change

We will know this strategy has worked if there is:

- growing public awareness of new biotechnology developments;
- public confidence in the way the sector carries out its work;
- significant movement towards sector growth targets;
- greater depth of expertise across the biotechnology sector which ensures opportunities are being seized to realise the benefits of New Zealand's world-class research;
- greater depth and breadth in biotechnology global linkages;
- public confidence that the regulatory system provides the necessary safeguards;
- confidence among researchers that the regulatory system is able to accommodate innovation;
- stronger co-ordination between key players in the biotechnology sector and relevant government agencies.

Annex One

The Current Regulatory Framework for Approving New Biotechnology Products



Annex Two – Glossary

Abbreviations

ACVM	Agricultural Compounds and Veterinary Medicines Act 1997
APEC	Asia Pacific Economic Co-operation
DG	Director General
CRI	Crown Research Institute
DoC	Department of Conservation
ERMA	Environmental Risk Management Authority
FAO	UN Food and Agricultural Organisation
FSANZ	Food Standards Australia New Zealand
FRST	Foundation for Research, Science and Technology
GIF	Growth and Innovation Framework
GMO	Genetically modified organism
GTAC	Gene Technology Advisory Committee
HRC	Health Research Council
HSNO	Hazardous Substances and New Organisms Act 1996
HRCEC	Health Research Council Ethics Committee
IBAC	Independent Biotechnology Advisory Council (ceased existence in July 2002)
IBSC	Institutional Biological Safety Committee
MAAC	Medicines Assessment Advisory Committee
MED	Ministry of Economic Development
MfE	Ministry for the Environment
MoRST	Ministry of Research, Science and Technology
NECAHR	National Ethics Committee on Assisted Human Reproduction
NERF	New Economy Research Fund
NZTE	New Zealand Trade and Enterprise (new Government agency, operative from July 2003, formed from the integration of Industry New Zealand, Investment New Zealand and Trade New Zealand)
OECD	Organisation for Economic Co-operation and Development
RCGM	Royal Commission on Genetic Modification
RSNZ	Royal Society of New Zealand
SCOTT	Standing Committee on Therapeutic Trials
UNESCO	United Nations Educational, Scientific and Cultural Organisation
VIF	New Zealand Venture Investment Fund
WHO	World Health Organisation
WTO	World Trade Organisation

Technical Definitions

Angel investment: Early, pre-seed funding for new start-up businesses; this investment is usually in the form of equity and involves 'hands on' business advice.

Biotechnology: Any technological application that uses biological systems, living organisms or derivatives thereof (whether genetically modified or not) to make or modify products or processes for general use.

Biodiversity, biological diversity: The existence of a wide range of different types of species (e.g. plant and animal) at a given time.

Bioinformatics: A computer-based discipline that organises biological data from DNA and protein sequencing and provides a technique for computer imaging and modelling of biological systems.

Bioprospecting: Examination of biological resources (e.g. plants, animals, micro-organisms) for features that may be of value for commercial development.

Bioremediation: The use of biological systems to clean up pollution and other environmental contaminants.

Chromosome: Components in a cell that contain genetic information. Each chromosome contains numerous genes.

Clone: An identical copy of something. The term may be applied to a piece of DNA, a cell or individual plants or animals such as identical twins.

Codex Alimentarius Commission: This Commission was created in 1963 by the Food and Agricultural Organisation (FAO) and the World Health Organisation (WHO) to develop world food standards, guidelines and related texts such as codes of practice under the joint FAO/WHO Food Standards Programme.

DNA: Deoxyribonucleic acid, the chemical at the centre of the cells of all living things, which controls the structure and function of each cell and carries genetic information during reproduction.

Gene: A sequence of DNA on a chromosome that contains an instruction for a cellular function that is inherited.

Genetic modification: Altering the genetic material of cells or organisms to make them capable of making new substances or performing new functions. Also referred to as genetic manipulation and genetic engineering.

Gene therapy: The process of introducing new genes into cells to correct a genetic disease.

Horizontal gene transfer (HGT): Refers to the movement of a gene from one species to another. HGT is a naturally occurring process, especially among bacteria. HGT between plants and bacteria may occur, but only extremely rarely. It is distinct from the normal process of vertical gene transfer (from parent to offspring) which occurs in reproduction.

Intellectual property: The area of law involving patents, copyrights, trademarks, trade secrets and plant variety protection.

Matauranga Maori: This is a Maori world view that embraces science and the development of science from within a cultural framework.

Nanotechnology: Sometimes called "molecular manufacturing" or "micro-robotics" . It involves the development and use of devices that have a small size (of only a few nanometers).

Nutraceutical, nutriceutical: A food product that includes improved nutritional characteristics and/or pharmaceutical properties.

Patent: The exclusive right to make use of an invention for a fixed time.

Plant variety rights: The exclusive right to produce a new plant variety for sale and to sell propagating material.

Stem cells: Cells that have the ability to continuously divide and develop into various types of tissues. Can be sourced from early embryos, foetuses, umbilical cord blood and adult tissues (e.g. bone marrow).

Therapeutic cloning: A technique whereby people can provide their own somatic (adult cell) nuclei to replace nuclei in their own or donated eggs, so that individual embryonic stem cells can be developed. The embryonic stem cells can then be used to replace tissue that has been damaged by injury or disease. This technique is being investigated for the treatment of Parkinson's and Alzheimer's diseases.

Transgenic: An organism that has been genetically engineered to contain genes from another species.

Wai 262: Claim to the Waitangi Tribunal from six iwi and one whanau, which claim exclusive and comprehensive rights to indigenous flora, fauna and other 'taonga' such as traditional knowledge.

Annex Three – Biotechnology-Related Web Links

NEW ZEALAND LINKS

Biosphere New Zealand – www.biospherenz.com

An industry initiative to showcase business and investment information on New Zealand's rapidly growing biotechnology sector.

BIOTENZ – www.biotenz.org.nz

BIOTENZ is a group of leading New Zealand providers of biotechnology, natural, pharmaceutical and biological products and services. BIOTENZ is supported by Trade New Zealand.

Crown Research Institutes

AgResearch – www.agresearch.cri.nz

Crop and Food – www.crop.cri.nz

Forest Research Institute – www.forestresearch.co.nz

Geological and Nuclear Sciences – www.gns.cri.nz

HortResearch – www.hortresearch.co.nz

Industrial Research – www.irl.cri.nz

Institute of Environmental Science and Research – www.esr.cri.nz

Landcare Research – www.landcareresearch.co.nz

National Institute of Water and Atmospheric Research – www.niwa.cri.nz

Environmental Risk Management Authority – www.ermanz.govt.nz

ERMA New Zealand controls the introduction of new plants and animals, including GMOs and new and existing hazardous substances to New Zealand.

The Independent Biotechnology Advisory Council – www.ibac.org.nz

Although IBAC ceased to operate in August 2001, its website remains an excellent source of research and reports.

Industry New Zealand – www.industrynz.govt.nz

This website showcases New Zealand's brightest businesses, entrepreneurs and opportunities.

Ministry of Agriculture and Forestry – www.maf.govt.nz

MAF is about agriculture, horticulture and forestry, safe food, a protected environment, the wise use of the land, the creation of clean, green product and the economic success of those who produce it.

Ministry for the Environment – www.mfe.govt.nz

MfE works with others to identify New Zealand's environmental problems and get action on solutions. Its focus is on the effects people's everyday activities have on the environment, so its work programmes cover both the natural world and the places where people live and work.

Ministry of Health – www.moh.govt.nz

MoH is the Government's primary advisor on health policy and disability support services.

Ministry of Research, Science & Technology – www.morst.govt.nz

New Zealand Biotechnology Association – www.biotech.org.nz

The New Zealand Biotechnology Association website provides a gateway to a directory of New Zealand biotechnology companies, university departments and research institutes. Also included are reports on annual conferences and other international biotech conferences planned for the future.

New Zealand Government Genetic Modification Website – www.gm.govt.nz

This site aims to give New Zealand citizens access to a broad range of information relating to genetic modification, how it is used and how it is controlled.

Royal Society of New Zealand – www.rsnz.govt.nz

The Royal Society is an independent academy of sciences and an association for the advancement and promotion of science and technology. The Royal Society administers a number of funds on behalf of the Government, including the Marsden Fund and the Centres of Research Excellence Fund.

The Royal Commission on Genetic Modification – www.gmcommission.govt.nz

INTERNATIONAL LINKS

BIOTECanada – www.biotech.ca

BIOTECanada is the national organisation dedicated to promoting to Canadian citizens a better understanding of biotechnology. The site represents Canadian healthcare, agricultural, food, research and other organisations involved in biotechnology.

Biotechnology and Biological Sciences Research Council – www.bbsrc.ac.uk

This council is Britain's lead funding agency for academic research and training in the non-medical life sciences. The site offers news and events, bioscience research updates and science and society discussion documents.

Biotechnology Australia – www.biotechnology.gov.au

Biotechnology Australia was established in the 1999-2000 Commonwealth Budget. It is a multi-departmental government agency – responsible for co-ordinating non-regulatory biotechnology issues for the Commonwealth Government – and seeks to provide balanced and factual information on biotechnology in the Australian community.

Biotechnology Ireland – www.biotechnologyireland.com

This interactive website is maintained by BioResearch Ireland. It provides a current view of developments in the Irish biotech sector, offering conference details, news and research papers.

European Federation of Biotechnology – www.efbweb.org

The European Federation of Biotechnology is the non-profit association of all national and cross-national learned societies, universities, institutes, companies and individuals interested in the promotion of biotechnology in Europe.

OECD Biotechnology – www.oecd.org

The OECD Biotechnology website provides an overview of work currently being undertaken by the OECD in this field. Coverage includes biotechnology and agriculture and biotechnology in science/technology and industry together with updates and news releases.

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NEW ZEALAND BIOTECHNOLOGY STRATEGY

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