GROWING THE BIOTECHNOLOGY SECTOR IN NEW ZEALAND | A FRAMEWORK FOR ACTION

REPORT FROM **THE BIOTECHNOLOGY TASKFORCE**

MAY 2003

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In early 2002 the Government released its Growth and Innovation Framework. The goal of the framework is to return New Zealand to the top half of the OECD in GDP per capita rankings. It's an unambiguous objective.

One of the many initiatives outlined in the Framework is to select areas of potential that are worthy of special attention and direct government effort towards them. These were identified as Information and Communications Technology, Creative Industries, and Biotechnology. We established sector-led taskforces in all three areas. Their aim: to agree priorities and develop action plans to stimulate the growth and develop the international competitiveness of their respective sectors.

Why biotechnology?

Biotechnology is not simply an industry in itself – it both contributes to and influences numerous other parts of our economy and society. New Zealand's economy is built on this country's exceptional ability to add value to agricultural products by applying biological knowledge. But biotechnology in New Zealand no longer stops there. Biotechnology today has large and wide-ranging effects on such diverse areas as health care, criminal justice and biosecurity. Our biomedical sector, though small, is one of the fastest growing biotechnology areas in New Zealand.

The taskforce members come from a wide range of backgrounds – from commercial companies to universities and Crown Research Institutes. But they all share a genuine passion for the industry and its potential and, more importantly, a real commitment to the welfare and success of New Zealand.

They have delivered some bold recommendations; a few may even be controversial, but I welcome them nevertheless. The Government did not establish the taskforce to be told what we wanted to hear; we wanted to be told what they thought we needed to know. The Government will continue its work on the Growth and Innovation Framework and will consider how we can move forward in partnership with the industry on the taskforce recommendations in that context. The recommendations, however, are not just for Government; they are also for industry to implement, on their own or in partnership with us. This is key if we are to realise the aim of the Growth and Innovation Framework.

Pete Hodgson

Minister of Research, Science and Technology

TASKFORCE MEMBERSHIP

Chairman

Bill Falconer	Chairman, BIOTENZ Inc, Meat Industry Council, Hellaby Holdings, Kiwifruit International, Oyster Bay Marlborough Vineyards and Restaurant Brands; and director Biologics Ltd

Members

Professor Garth Cooper	Professor in Biochemistry and Clinical Biochemistry, School of Biological Sciences and Department of Medicine, Auckland University
Michael J Harrington	General Manager, Eli Lilly and Company (NZ) Limited; and vice-chairman, Board of the Researched Medicines Industry
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The Government convened the Biotechnology Taskforce in 2002 to agree priorities and develop action plans for stimulating the growth and international competitiveness of New Zealand's biotechnology sector.

We have taken this task to heart. After talking to industry, arms of government and international observers, we have concluded that New Zealand has a unique place in the world and an opportunity to gain leverage from the biotechnology industry to grow the nation.

When we consider the range of activities that come under the heading 'biotechnology' we can see that New Zealand has the opportunity to create value, not just in biomedicine or agri-biotechnology, but also in a host of associated areas.

New Zealand's excellent reputation in science, agriculture, horticulture, forestry and marine sciences is a firm foundation on which to bring about changes in related industries and the whole primary sector. And, building on our world-class medical research, we can tap into a huge global market for pharmaceutical and biomedical products.

To ensure this happens, our main focus in this report is on two major inputs to the industry: people and funding. We also recognise that getting people and funding together requires effective networks and this report discusses global networks and institutions in that context. Regulations and infrastructure that support the industry are also examined. Our report provides recommendations and actions for both the Government and the biotechnology industry. We believe the two must work together to enable New Zealand to reinforce its position on the world biotechnology stage.

Our primary recommendations centre around three essential areas:

- The need to build critical mass;
- The introduction of a package of regulatory reform to create a competitive environment for growth; and
- The establishment of a robust international network through which to stimulate the flow of international investment.

Whilst we have completed our deliberations on the overall set of recommendations to grow the sector we acknowledge that the real challenge starts now. That is the challenge to implement a programme of activity to deliver the vision with sustained commitment from all the stakeholders referred to in this report. As a taskforce we, collectively, are committed to take our report forward and to fully engage in the process of implementation. It is our intention to regularly monitor progress and reinforce actions as we embark on this exciting journey to unleash the full potential of our burgeoning biotechnology talent.

EXECUTIVE SUMMARY

This report represents the culmination of the work of the Biotechnology Taskforce to date from which a Framework for Action has been assembled which challenges industry, government and many other key stakeholders to work together to bring about long-term sustainable growth in our biotechnology sector. As such this report sits at the start of a significant process of change and opportunity from which New Zealand can position itself as a vital global player in the modern biotechnology marketplace.

Underlying this framework we have a bold vision for growth in the New Zealand biotechnology community over the next 10 years, with the number of companies having a core biotechnology focus increasing fivefold to more than 200 and the number of biotechnology organisations expanding threefold to over 1,000. We expect biotechnology to employ more than 18,000 people by the end of that period. Independent reviews prepared by Ernst & Young and The Channel Group provide supporting validation of the growth vision and direction.

This projected growth has many flow-on effects. What infrastructural evolution is required to meet the required growth in critical mass? Will New Zealand have the number and calibre of skilled staff with scientific, intellectual property and business experience to fill the extra jobs? How should the investment/venture capital base be encouraged to fuel this growth? What changes are required in the tax and regulatory regimes to help organisations grow? How should technology transfer from research organisations be handled to ensure sector growth and contribution to foreign exchange earnings? How do we ensure that scientific ventures have a better chance of commercial success?

This report outlines what can be done immediately by the biotechnology industry and by the Government to answer these questions and others. It also indicates areas that should be addressed over time. New ideas to bring New Zealand to the forefront of the global biotechnology stage are discussed.

Across the world, governments have recognised the importance of their role in supporting the biotechnology industry's growth. A recent report from the Massachusetts Biotechnology Council provides evidence of the continued call on support from government to support the sector's growth. The key, then, lies in the biotechnology community's ability – in partnership with government – to initiate bold steps forward. While we acknowledge that the Government is already moving in some areas like tax policy and the Patents Act review, we believe reform is too slow. The commercial environment in biotechnology is fast moving and the window of opportunity to act is open now.

To this end, we have developed a Framework for Action that is forward-looking and seeks major changes. It is constructed under the headings of People, Funding, Institutions, Infrastructure, Regulation and Global Participation.

CASE STUDY

Professor Sir Graham Collingwood (Mont) Liggins

The key to child birth was found in sheep on Auckland's One Tree Hill and at the National Women's Hospital.

Until Mont Liggins completed his ground-breaking research on these sheep, it was not understood that it was the foetus that told the mother it was mature and ready to come out into the world.

Through unlocking this mystery, he established the hormonal triggers for parturition and his discovery has changed the way clinicians handle every human and animal birth.

Using Mont Liggins' sheep model, New Zealand researchers have made real advances in the biotechnology ranging from methods to save the lives of premature babies through to preventing brain damage in infants.

Many believe Mont Liggins has made one of the largest single scientific contributions to the advancement of human health worldwide.

The framework takes into account the different dynamics operating in the sector, reflected in part by the overlap in biomedical and primary sector science. The framework recognises two classic forms of sector organisation in terms of the route to commercialisation within this overlap:

i) Those facing high regulatory barriers with long lead times to market; and

ii) Those facing the converse but who nevertheless face equivalent barriers in areas such as capital investment and infrastructure.

We have highlighted below some of the significant barriers identified in the Framework for Action.

Framework Highlights

People – The importance of training, recruiting and retaining a high calibre and dynamic workforce to underpin the growth that is required cannot be overstated. We need significant growth in this talent pool of scientists, business people and scientific entrepreneurs with qualifications, skills, experience, curiosity, drive and entrepreneurship. This need mirrors a goal of many countries and major trading states throughout the world, some of which consider that the fastest way to meet this objective is to recruit scientists. New Zealand must decide how to compete in this market by reinforcing the message that this is a top country in which to work and conduct business internationally and where individuals can fulfil their ambitions. Within this we must also recognise that quality domestic learning and research institutions are critical. We must do more to value the potential of science-based careers in biotechnology and to promote the breadth of job opportunities and career pathways.

A key need is for the biotechnology industry, with government, to conduct further research into capability gaps. If the biotechnology sector is to meet its vision and growth targets for 2013, demand for skills will need to be identified and tertiary institutes, industry and targeted recruitment must meet this demand. The taskforce strongly recommends that the sector's future human resource needs be evaluated and measures be put in place to meet this demand. Understanding must develop about the extent of shortages, their long-term effects, and new gaps liable to open in future.

Funding – Access to capital is the other major hurdle facing the sector. Proof-of-concept funding for new commercial ideas is an area where governments overseas have been active, and moves by the New Zealand Government in the area are welcome. However, the biotechnology industry is distinct from most industries in that it has inherently high research and development costs and long commercialisation timeframes (typically 3–4 times longer than other high technology sectors).

The approach to funding must reflect this and address the requirements for funding from the research stage, through an idea's refinement with potential and proof of concept, to field testing, clinical trials, regulatory approvals where needed, manufacture, marketing and distribution. All must be undertaken before commercial returns can flow.

We need a long-term funding perspective, and the funding framework should be designed to capture high-risk investment funds at each step of commercialisation.

We believe this can be done through the sector having its own Biotechnology Investment Fund tuned to all aspects of the development cycle. The fund will allow analytical expertise and knowledge about New Zealand's biotechnology to be developed. This will lead to greater assurance for experienced overseas investors, and enable New Zealand to access funding not previously open to biotechnology firms here.

Institutions – New Zealand must develop research establishments which focus on, among other things, programmes that will attract scientists and augment the critical mass we seek. Consideration is given to the idea of these institutions operating structured business training programmes for those scientists with a flair for commercialisation. Processes to stimulate commercialisation of promising ideas, including the formation of spin-out organisations and enhancing collaboration with businesses, should be part of annual plans.

The Biotechnology Investment Fund calls for an ongoing link between research needs and new ideas. Fundamental research will continue to fuel new commercial opportunities and improve technology. Government must continue to be the active player in core research funding. The taskforce recognises that an investment in research should be treated as 'investment' and not as a cost to government. We have identified the Marsden, New Economy Research and Public Good Health Research Funds as the areas requiring significant injections of new investment. A commitment by New Zealand-based pharmaceutical companies to increase research and development operations is essential. Government needs to look at ways of stimulating increased pharmaceutical research activity. The relationship between PHARMAC, government and the pharmaceutical industry needs careful review. The recent Government legislation to allow pre-expiry testing of pharmaceutical products is an example of tension in the relationship. All players must forge a constructive working relationship to address patent law and drug purchasing issues.

Crown Research Institutes (CRIs) have evolved from a period of revolutionary science reforms. The CRI structure has delivered benefits across science and the economy and we welcome the clarification by the Government of its expectations of CRIs in commercialisation. Proactive partnerships and investment between the CRI structure and industry is vital.

Infrastructure – We must encourage interactive clusters of institutions and companies in related fields. Structured networking programmes for scientists and business people also are required. The value of collaborative presentation and marketing of the sector's capabilities under a national brand is essential, as is the need to ensure an adequate supply of laboratory and office space for new companies.

Industry and the Government must stimulate growth in critical mass. The Centres of Research Excellence, selected through the operation of the Royal Society Centres of Research Excellence Fund, including the Centre for Molecular Biodiscovery at Auckland University, are positive. More needs to be done, however. This means providing funding for large capital purchases of equipment and technology for identified areas of strength. To avoid unnecessary duplication of capital purchases, institutions must collaborate to make decisions about what capital is required. Consideration is given to establishing a dedicated 'Request for Interest' to determine what infrastructural capacity building is required and how this should be tied in with appropriate skills development. This is important in view of the fact that the Wellcome Trust is withdrawing funding in this area. Such a move would also build stronger research and commercial networks.

A stronger industry network is paramount. The establishment of a single unified industry body is a step in the right direction and must be fully supported by industry. Government can help to sustain this industry body in its early stages by providing seed funding.

The industry needs integrated support from the wider community as it charts new territory and develops biological industries. The industry as a whole will succeed if diverse community perspectives can be not only respected but also used and integrated into thinking on sector development.

Regulations that support the sector – Regulations must be efficient, cost effective and equal to international best practice and, where appropriate, must be acceptable to our major trading partners.

Industry must have a regulatory environment that is transparent and predictable. New Zealand has one of the most comprehensive regulatory regimes in the developed world. However, compliance costs and delays related to public consultation are climbing. The public consultation process requires streamlining to improve cost and time overheads without compromising quality control.

A two-yearly review of regulation compliance costs is recommended. This audit should consider, from a practical perspective, how all aspects of the regulatory system allow companies and researchers to operate. This should be linked to a process for speeding up any regulatory reform. The present system is overly prescriptive and easily drawn out.

In addition, our patent law still reflects New Zealand's former status as a technology importer. Urgent reform is needed in recognition of the fact that New Zealand now has its own valuable technology to protect, and that its high technology industries, and the biotechnology sector in particular, will grow in collaboration with international firms and institutions. Our patent laws must become more compatible with those of our overseas partners.

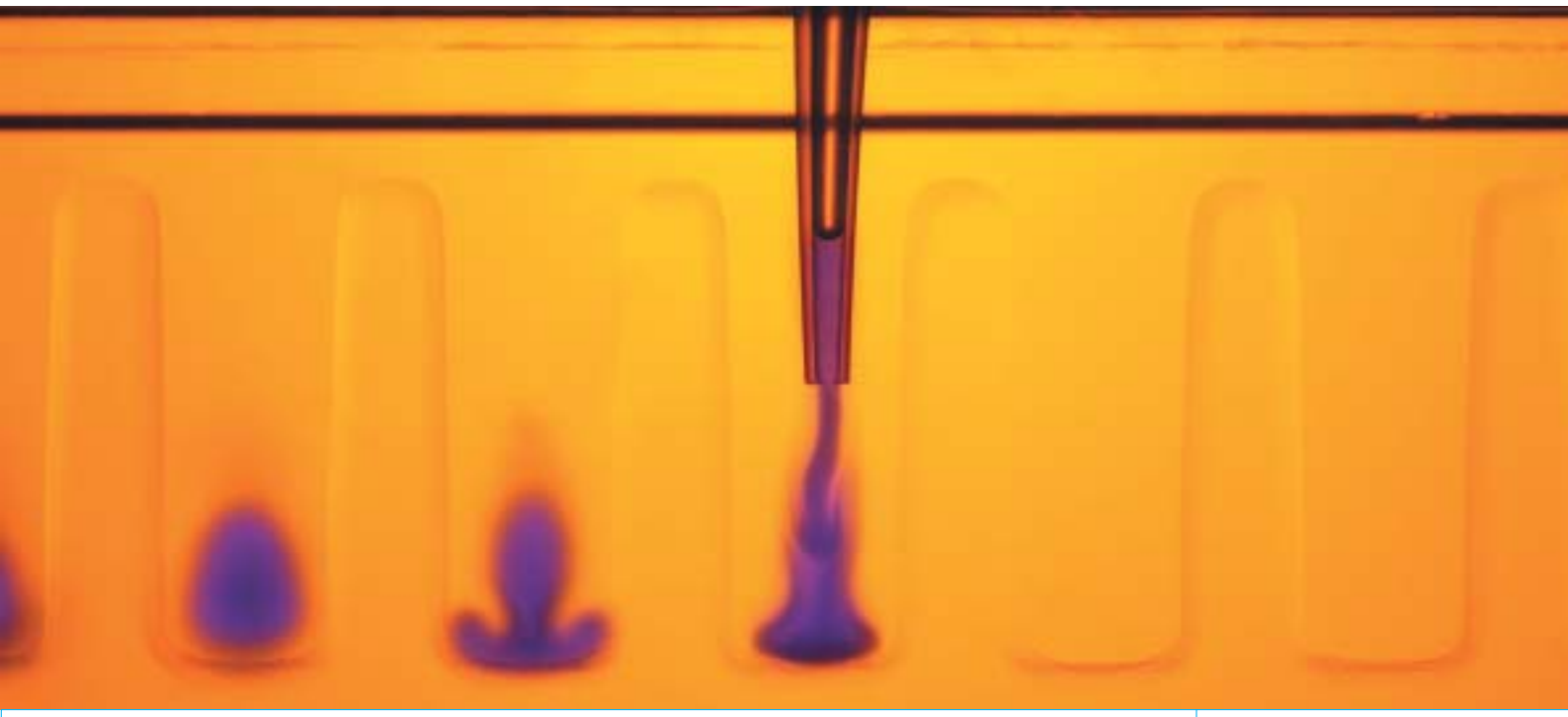
Global participation – New Zealand research funding, institutions and businesses must pinpoint where they can best expect to contribute. We must define the right role for New Zealand in what is a truly global sector – be it in ongoing research and development, clinical testing, nutritional foods, drug discovery, or specialist manufacture – and organise ourselves to retain maximum development, and reward, in New Zealand. New Zealand companies must participate in international deals and be able to make trade-offs in different markets.

Companies can locate anywhere. New Zealand must realise it is competing with countries that have developed tax and other support measures that reflect the high risk and long lead time features of this sector. We do not suggest that New Zealand design a sector-specific tax regime (though we note that one exists for the petroleum exploration sector which has very similar high risk and long lead time characteristics), but we draw attention to the option of fine tuning in such areas as tax loss continuity, and offset, employee share options, intellectual property acquisitions, and research and development costs.

Active promotion of biotechnology abroad is intrinsically linked to foreign direct investment and market access. A five-year commitment by industry and Government to promote New Zealand biotechnology in major exhibitions (e.g. BIO and AusBio) and investment forums in target markets is warranted.

In conclusion, it is time to be bold. We must not let the opportunity to harness biotechnology for greater economic growth pass us by. We believe it is time for New Zealand to take advantage of the vast opportunities biotechnology offers and to build on our substantial heritage, capabilities and innovative prowess.

The Framework for Action contains a spread of recommendations over each of the six topic areas highlighted. Some can be addressed now, some require a longer term perspective, whilst for others we are calling for initial activity to be reviewed on an ongoing basis. Balanced development of all the recommendations is key to delivering the transformational change this report is calling for.



	Recommended Action	Responsibility	Timeframe
PEOPLE			
Action 1	That industry, with Government, define a programme for targeting the recruitment and repatriation to New Zealand of five key scientists and entrepreneurs (i.e. 'rainmakers') per annum with the skills and experience to establish new and innovative research labs within an effective commercialisation structure. This may include working with programmes such as World Class New Zealanders and the Kiwi Expat Association as a way to attract talent.	Government (Industry New Zealand) Industry	Immediate action
Action 2	That industry, with support from Government, performs a capability analysis drawing on the suite of audits in existence (e.g. Biotenz capability audit) to identify gaps in skill sets. This analysis should include recommendations on how to engage with the education sector to develop programmes to bridge the identified gaps.	Industry and Government (Ministry of Research, Science and Technology, Tertiary Education Commission, Industry New Zealand)	Rolling action

	Recommended Actions	Responsibility	Timeframe
FUNDING			
Action 3	That investment in biotechnology research continues to grow to a level of $300m pa over the next five years. Industry to explore mechanisms for the provision of strategic co-funding in basic biotechnology research.	Government (Ministry of Research, Science and Technology) Industry	Long-term action
Action 4	That industry and Government establish a horizontal Biotechnology Investment Fund in the order of $200m to stimulate the commercial development of viable biotechnology research and to encourage growth in new companies.	Industry Government (Industry New Zealand, Ministry of Research, Science and Technology)	Immediate action
Action 5	That Government establishes a vertical biotechnology proof-of-concept fund to stimulate the pull-through of basic research.	Government (Ministry of Research, Science and Technology)	Immediate action
Action 6	Government to undertake a broader study of the tax structure applicable to the New Zealand biotechnology sector, taking into account its particular characteristics of heavy front-end research costs and long lead times to commercialisation.	Government (Inland Revenue Department, The Treasury)	Rolling action

	Recommended Actions	Responsibility	Timeframe
INSTITUTIONS			
Action 7	That industry, Crown Research Institutes and tertiary providers develop a best practice programme covering the interface between industry and science. This programme should aim to stimulate market-led biotechnology research within a framework that recognises: ■ The mutual benefits of industry–science partnership; ■ The need for open and effective management of intellectual property; ■ Opportunities for research teams to gain an insight on drivers within the commercial biotechnology market; ■ Proactive investment by industry to extract greatest possible commercial value from biotechnology research; and ■ The role of Government in monitoring its expectations of Crown Research Institutes to commercialise research output.	Industry Government (Crown Research Institutes, tertiary education institutions)	Long-term action
Action 8	That Government reinforces its expectations of Crown Research Institutes and tertiary education institutions to spin-out commercially viable research into stand-alone businesses.	Government (Crown Company Monitoring Advisory Unit, Tertiary Education Commission)	Immediate action
Action 9	That Government takes steps to reinforce the relationship with the pharmaceutical industry to stimulate research investment. These steps will include: ■ Introducing certainty and predictability into PHARMAC's funding, by setting ongoing three-year rather than year-to-year funding; ■ Developing an action agenda for the industry, building on the RMIANZ report "A Pathway to Economic Growth"; and ■ Reviewing the channels through which Government engages with the pharmaceutical industry.	Government (Ministry of Economic Development, Ministry of Research, Science and Technology, The Treasury, Industry New Zealand, Ministry of Health) Industry	Immediate action

	Recommended Actions	Responsibility	Timeframe
INFRASTRUCTURE			
Action 10	That industry consolidates its networks, and focuses the efforts of existing networks such as Biotenz, the Biotechnology Association, BioSouth and Bio Auckland, to create one strong industry body with sufficient funds to augment the whole sector. Consolidation should address: ■ The development of a strategic plan to concentrate infrastructure and research investment in key biotechnology areas; ■ The facilitation of partnerships between the primary sector, research institutions and feeder industries; ■ Continuation of the development and building of new clusters and communities; and ■ Progressing existing Government-led sector support projects.	Industry	Long-term action
Action 11	That Government supports the establishment of a single biotechnology industry body through providing seed funding of $450,000 per year for the next three years.	Government (Industry New Zealand)	
Action 12	That Government coordinates a programme to identify large asset platform technology gaps, and mechanisms to fund those. This should include the implementation of a dedicated 'Request for Interest' to determine what infrastructural capacity building is required.	Government (Industry New Zealand, Ministry of Economic Development, Ministry of Research, Science and Technology, Foundation for Research, Science and Technology)	Immediate action
Action 13	That industry works with all education providers to develop a world-class suite of biotechnology education programmes building on state-of-the-art visualisation and learning techniques.	Industry	Long-term action

	Recommended Actions	Responsibility	Timeframe
INFRASTRUCTURE continued			
Action 14	That industry works with Government on the goal of 'building understanding and positive engagement between the broader community and the biotechnology sector'. This should result in projects that: ■ Recognise the value of different perspectives on growth of the sector; ■ Gain support, including from appropriate Maori authorities; and ■ Cultivate effective and innovative education programmes to communicate the cultural, economic and environmental benefits which the application of biotechnology can achieve.	Industry and education providers	Long-term action
REGULATIONS THAT SUPPORT THE SECTOR			
Action 15	Government to undertake a biennial review of the compliance costs associated with biotechnology, bearing in mind the processes required to accelerate any regulatory reform identified.	Government (Ministry of Economic Development)	Rolling action
Action 16	In establishing a standards framework for research and clinical trials, the research community and industry should: ■ Strive to adopt FDA accredited standards for research and clinical trials; and ■ Seek ways to engage in the debate in wider international standards bodies such as the International Conference on Harmonisation (ICH).	Industry	Long-term action
Action 17	That a review be undertaken to ensure that streamlined and coordinated regulation practices operate under the HSNO, ACVM and Medicines Acts to avoid duplication.	Government (Ministry of Research, Science and Technology)	Rolling action

	Recommended Actions	Responsibility	Timeframe
REGULATIONS THAT SUPPORT THE SECTOR continued			
Action 18	That the following changes be made to the ERMA hearings and HSNO Act approval processes to ensure New Zealand has a world-class regulatory system that meets environmental protection requirements and is quick and cost efficient: ■ ERMA to adopt stricter compliance with rules of evidence procedures within its hearing process; ■ Channel all generic submissions not specifically related to an application for HSNO Act approval through an appropriate ethics council (e.g. bioethics) on the basis that a mechanism should be in place to ensure all year-round response; and ■ Adopt a more balanced cost recovery practice in the operation of the approval process.	Government (Ministry of Research, Science and Technology)	Immediate action
Action 19	That Government amends the current HSNO regulations relating to: ■ The growth of GM micro-organisms in containment vessels, to bring it into line with Australian legislation; and ■ Containment approval for small quantities of chemicals sold for research use, by broadening the exemption for experimental or research use of such materials, to bring it in line with US practice.	Government (Ministry of Research, Science and Technology)	Immediate action
Action 20	That Government amends patent legislation to accommodate biotechnology product development times so that the effective patent life is extended and New Zealand is in line with international best practice.	Government (Ministry of Economic Development)	Immediate action
Action 21	That the Government amends the New Zealand Plant Variety Rights Act 1987 to introduce the concept of essential derivation.	Government (Ministry of Economic Development)	Immediate action
Action 22	That Industry New Zealand, in partnership with industry leaders and Biotechnology Australia, develop an IP management manual specifically for biotechnology.	Government (Industry New Zealand) Industry	Immediate action
Action 23	That industry facilitates regular biotechnology IP management training workshops to develop intellectual property knowledge in New Zealand.	Industry Government (Industry New Zealand)	Rolling action

	Recommended Actions	Responsibility	Timeframe
GLOBAL PARTICIPATION			
Action 24	That the Government and industry actively promote New Zealand biotechnology abroad through effective branding, presence at international fora and hosting international conferences in New Zealand.	Government (Industry New Zealand) Industry	Long-term action
Action 25	That industry and Government set in place a programme of initiatives to stimulate the formation of international biotechnology partnerships. This may include: ■ Implementing an offshore marketing base (or bases) in regions with strong biotechnology markets; ■ Reinforcing links with counterpart Australian industry bodies to identify common barriers to the establishment of biotechnology start-up companies; and ■ Developing a programme working at individual company level to help identify overseas business partners (not limited to biotechnology) that can 'add value' on the route to market.	Government (Industry New Zealand, Ministry of Economic Development, Ministry of Research, Science and Technology) Industry	Long-term action
Action 26	Create a not-for-profit organisation, based in the US, to facilitate access to philanthropic and government funds from such groups as the National Institutes of Health and the Gates Foundation.	Government (Industry New Zealand)	Immediate action
Action 27	That Government and industry investigate the status and benefits of strategic alliances with global bodies including, for example: ■ NATO Foundation; and ■ Human Frontiers for Science Programme.	Industry Government (Industry New Zealand)	Immediate action
Action 28	That Government and industry review the benefits of a programme to position New Zealand as the key international arena for intellectual debate and focus on the coordination and development of international biotechnology protocols.	Industry Government (Industry New Zealand)	Long-term action

INTRODUCTION

Biotechnology as a scientific discipline has been in New Zealand for a century and a half and, as a nation, we have an international reputation for leadership in its application to agriculture, horticulture, forestry and marine life. Biotechnology, incorporating genetic analysis and research, will be the scientific feature of the 21st century, changing much of the world as we know it, as it has been changed with successive scientific developments during the 20th century.

Over the next decade, biotechnology developments will transform our agribusiness sector, which accounts for nearly 45 percent of current exports. From new horticulture cultivars to improved industrial processes in the dairy and meat industries, innovation will continue in our mainstay sectors. Biotechnology will change fundamentally the way we diagnose and treat diseases like diabetes and cancer. It is also an essential technology in environmental management. Improved water quality, biosecurity and pest management all rely on biotechnology. Our excellent science and reputation for being "sharp, smart and flexible", means New Zealand is well placed to take advantage of the ongoing biotechnology revolution.

Government, business leaders and community groups have voiced the importance of lifting New Zealand's economic growth to the top half of the OECD. The Growth and Innovation Framework launched in February 2002 identified biotechnology as one of three sectors with the potential to achieve this goal. The key issue is to develop an environment that enhances biotechnology's contribution to the mainstays of economic growth: foreign exchange earnings and gross domestic product (GDP) per capita.

New Zealand shares this aspiration with most developed and many developing nations, and is competing in the international marketplace for scientific talent, innovative developments, entrepreneurial skills and development capital. We must strive to create the environment that will give us a clear advantage over our global competitors. The challenge is to define and establish an industry-led framework in partnership with government for the development of biotechnology in New Zealand. Such a plan would not only envision New Zealand as a centre for biotechnological research, but would allow New Zealand to share in and benefit from the value to be gained from commercialising this research.

The New Zealand framework must therefore reflect where New Zealand scientists and the business community expect they can best contribute. Biotechnology can improve the efficiency of many of our primary sectors through the application of genetic knowledge and new techniques, many of which are derived from our biomedical research. It can also spawn 'innovation technology' resulting in the development of new products. Taken further, it has the potential to create 'step-function technology' which can change or create whole sectors (e.g. biofuel). The benefits achieved by better overlapping our biomedical and primary sectors will help produce the strong economic growth required to support first-world standards of living and health care in this country.

The taskforce believed it should first ask whether New Zealand, with its limited resources and the huge demands on them, can aspire to participate in this expanding global sector, given its requirements for scarce resources of people and capital. We concluded it could. New Zealand has already established a capability in biotechnology across a wide spectrum of its applications and already has a recognised place on the global biotechnology stage.

It is the view of the taskforce that to successfully meet this challenge within a decade it is important to increase the 'critical mass' of the biotechnology community and offer it greater international exposure. It is not just about creating a larger number of small biotechnology companies that develop scientific ideas, but instead having a greater spread of small, medium and large organisations in a broad-based biotechnology community that pursues global opportunities and employs people with varied disciplines.

1 OUR VISION AND TARGETS

We have an opportunity now to celebrate our strengths and heritage in biotechnology and to recognise our place in a global industry. More importantly, this report is calling for transformational changes, which will enable this country to build on the unique synergy between the primary sector and biotechnology sector to position New Zealand as both a world leader in biotechnology and as a good place to do business.

Our 10-year targets must be seen against the development of the biotechnology sector to date, which comprises:

- Significant research leading to commercialisation in the principal units in the agricultural industries – Fonterra (Vialactia), the Wool and Meat Boards (Ovita), and within a selection of companies in the meat industry;
- Significant research and commercial developments in the Crown Research Institutes;
- One major independent publicly listed initiative (Genesis); and
- Many spin-outs of single ideas into single purpose ventures, often experiencing extended development profiles dependent on successive increments of small amounts of capital.

While our vision targets significant growth over the period, rather than a simple growth in the number of enterprises, the growth must be in enterprises large enough to endure the turbulence of high-risk development. We must recognise the need for a different scale of approach.

We outline a bold vision "to ensure that within 10 years the biotechnology sector will not only make a major contribution to the process of lifting New Zealand into the top half of the OECD wealth rankings but will also elevate New Zealand's position as a global nation of biotechnology excellence in innovation, commercialisation and business practice".

Our targets over the next 10 years to deliver the vision are:

- A tripling in the size of the New Zealand biotechnology community to over 1,000 organisations, from 350;
- An increase in total cluster employment to over 18,000, from around 3,900;
- A five-fold increase in the number of core biotechnology companies to over 200, from 40; and
- Improving performance from both research organisations and private companies, resulting in increased export values from the current base of $250 million to over $1 billion per annum.

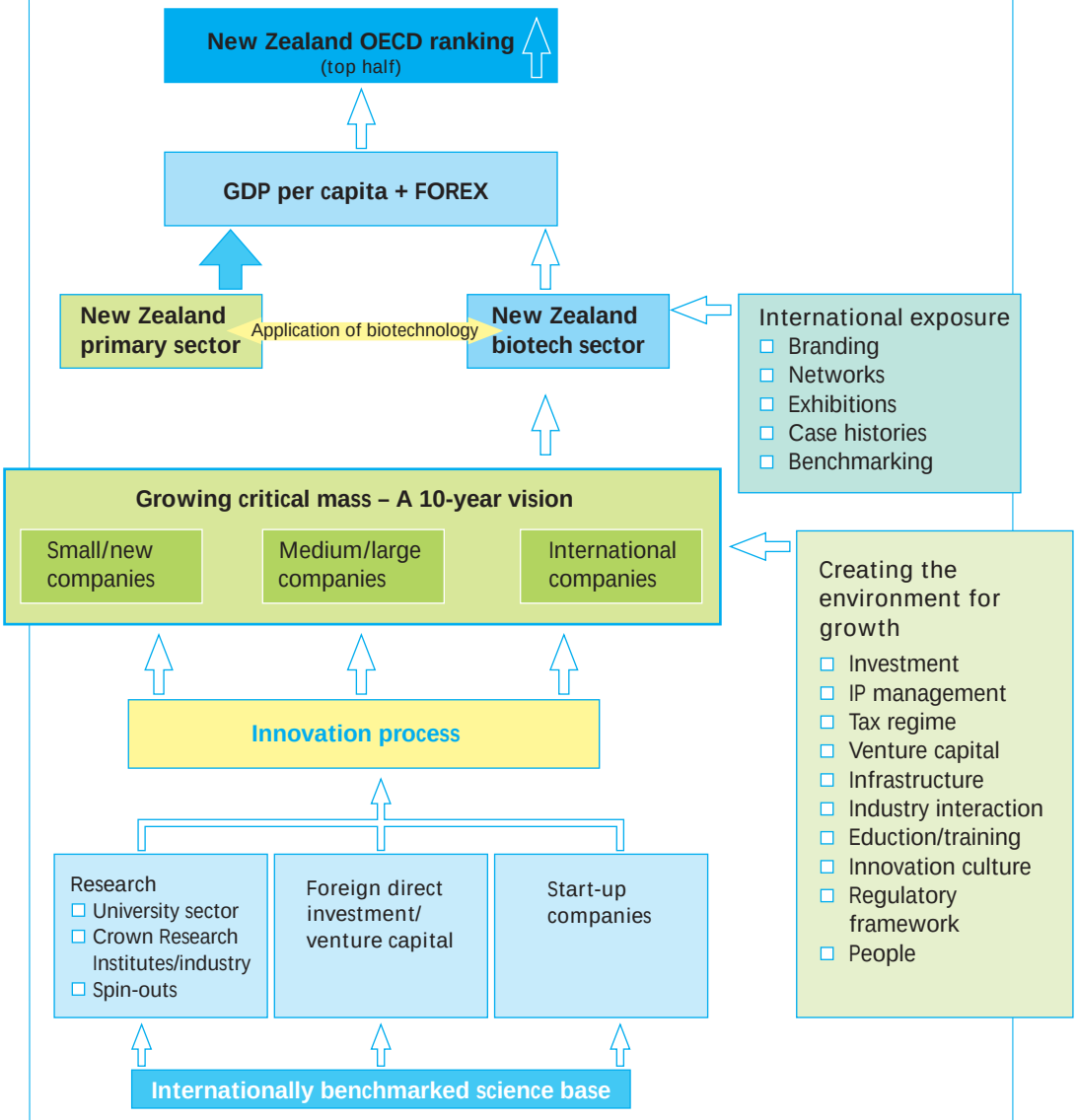
Growth in the size and number of core biotechnology companies is projected to achieve a market capitalisation of around NZ$10 billion, with at least two multi-billion New Zealand dollar companies.

Our target for growth in core biotechnology companies translates into a net gain in the order of 15 new companies per annum. It is important to recognise from the outset that some start-up and some already established core biotechnology companies will fail as the sector moves towards attainment of its vision. We also envisage a pattern of consolidation within the industry emerging over the next 10 years. This is a natural consequence of the process of transformational change in the sector.

As the industry and firms grow, relationships and connections within it will evolve. The involvement of New Zealand firms in the global biotechnology industry will increase and be more fully recognised. Small start-up firms will also relate differently to larger firms. We can expect more examples of small firms, rather than going to the capital market for support, going to larger companies with proposals. Our understanding about how the investment market functions for biotechnology will need to evolve also.

The capacity for biotechnology growth as an enabling technology to support the New Zealand primary agricultural sector cannot be underestimated in terms of impact on GDP performance. Figure 1 illustrates the key relationships, the significance of building critical mass and the expected effect of creating the right environment for growth and international exposure.

Figure 1
Biotechnology Sector Vision and its Contribution to Moving New Zealand up the OECD Ladder



Realising this vision will bring substantial economic benefit to New Zealand. Foreign exchange earnings and GDP per capita will increase. For example, if we hypothesise that the application of modern biotechnology over the next 10 years were to result in only a 3 percent improvement in the productivity of the New Zealand primary sector, then this improvement alone, at current economic levels (i.e. based on a 2002 measure of GDP), would yield an economic uplift in both GDP and export valuation in the order of NZ$500 million per annum. To put this in perspective, this level of uplift would represent 25 percent of the current annual growth in New Zealand GDP overall. If we extrapolate this figure over the 10-year vision for this report then the significance of the interrelationship between biotechnology and the primary sector is even more evident. We believe that modern biotechnology offers the potential for significantly greater productivity gains in some areas.

Strengthening local and international networks by promoting the Biosphere New Zealand brand and enhancing New Zealand's global reputation for 'applying biotechnology' will be critical to delivering the vision.

1.1 Structure of New Zealand's Biotechnology Sector

How achievable is this vision? To answer this question we must first know the size and make-up of the biotechnology sector in New Zealand. And we must clearly define the sector.

Four broad capability areas fall under a broad description of biotechnology as:

"the application of science and technology to living organisms as well as parts, products and models thereof, to alter living or non-living materials for the production of knowledge, food, drugs and other products and services and to improve quality of life".

The four areas are:

Research Capability including government-funded research and development (R & D) programmes and applied research.

Core Biotechnology Development typically covering the development and application of biotechnology to the areas of animal health care, environmental management, plants, crops and human health care.

Commercialisation and Distribution covering the commercialisation and distribution of products (including natural products) that are based on biotechnology research. Entities involved include large pharmaceutical and agribusiness companies, and organisations that commercialise products developed by entities involved in core biotechnology.

Support Infrastructure covering the provision of goods and services to the whole sector, including engineering, corporate, financial and legal advisory businesses, industry associations, and equipment suppliers.

It is recognised that several organisations have capabilities that span a number of these areas. This is to be expected and encouraged as part of the process of building depth in the sector. Out of the sector baseline of 350 organisations (see www.biospherenz.com for further details) approximately 40 have been classified as having a primary focus in core biotechnology (excluding large pharmaceutical and agribusiness companies, and medical device companies).

Biotenz is completing a capability audit across its membership which will be a valuable input when it comes to implementing many of the framework actions called for in this report. Initial results from the audit indicate that we have a comprehensive understanding of the size and shape of the sector baseline from which to drive the vision for growth and which is consistent with the high level baseline assessment of the targets undertaken by Ernst & Young.

Figure 2 gives a broad illustration of how the biotechnology sector in New Zealand may be described.

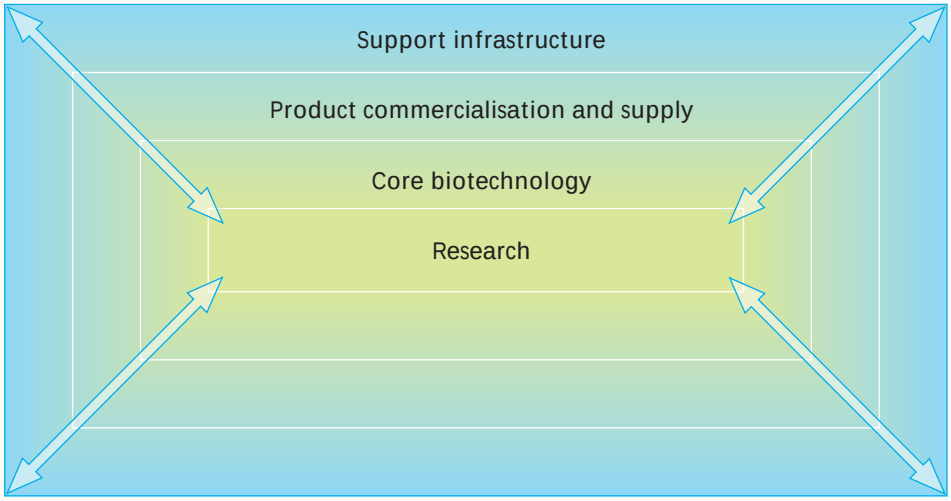


Figure 2 – Synoptic Overview of the New Zealand Biotechnology Sector

Ernst & Young were commissioned to conduct a review of the New Zealand biotechnology sector and make international comparisons with a number of reference economies. Their report considered the sector's size and makes comparisons with selected international reference economies where biotechnology is a strength. Their findings are encouraging. Their report focused on how achievable our growth targets are and measured forecast growth here against actual growth in seven countries, Scotland, Israel, Belgium, Ireland, Netherlands, Finland and Sweden.

Ernst & Young also provided a summary of common elements existing in each of these economies that appear to have contributed to creating the environment for biotechnology growth in these countries in four broad areas: People, Funding, Institutions, Infrastructure.

The Ernst & Young report states that "There is evidence of significant growth in the seven international benchmark countries. A number of countries have more than doubled the size of their biotechnology sectors, and two countries have increased the number of core biotechs by five times over a ten-year period". The Ernst & Young report goes on to observe that "Each of these countries have however typically had in place a package of governmental and industry wide coordinated initiatives designed with a specific objective of facilitating or accelerating that growth".

With respect to the achievability of the targets for growth for the New Zealand biotechnology sector over the next 10 years, Ernst & Young conclude that "subject to a coordinated approach between Government and industry... we consider that Targets 1,2 and 3 of the Taskforce Report (regarding growth in number of firms and employment within them) are reasonable". Whilst expressing more difficulty in forming a view regarding likely revenue and export growth they do state in regard to Target 4 (export growth) that "we believe it to be reasonable in the context of the other targets being met"and note that "…relative to the reference economies, New Zealand is uniformly smaller and more remote relative to major markets for products and capital... Intuitively however, each suggests that a coordinated approach between Government and industry participants will be an all the more essential ingredient to success…"

1.2 Our Strengths and Position on the Global Biotechnology Canvas

Can we aspire to play a key role in the global biotechnology industry? The answer is unquestionably yes. But what does the outside world have to say? A further independent review of the New Zealand biotechnology sector has been commissioned from biopharmaceutical consultants The Channel Group (TCG) to provide additional validation of the views and recommendations set out in this report. The TCG report analysed the sector from a different approach, considering emerging global market opportunities and mapping these against some of the unique strengths and niche potential that New Zealand has to offer.

The TCG report has identified nine important biotechnology sectors, which offer great potential for further development in New Zealand. They are:

Biopharmaceuticals	Biomanufacturing	Agricultural Biotechnology
Marine	Transgenic Animals	Bioactives
Industrial and Environmental	Nutriceuticals	Clinical Trials and Research

CASE STUDY | **IRL BioPharm** – Biomanufacturing

New Zealand's drug discovery abilities, and strength in biological-based pharmaceutical facilities, provide an opportunity for it to become a niche developer and manufacturer of trial quantities of new 'smart' drugs, at least to 'proof-of-principle' stage.

Industrial Research Ltd's (IRL) biopharmaceuticals operation has established a $12 million a year business with multinational pharmaceutical companies to produce components for anti-cancer drug trials.

IRL has a strategy of increasing its participation in the commercialisation of its world-leading science and technology. Keeping the bulk of the drug development process in New Zealand means IRL can maximise its return on its R & D investment.

As part of the strategy, IRL opened a $7 million glyco synthesis facility in Lower Hutt in March 2003. The facility builds on the carbohydrate chemistry team's skills in small molecule drug design and synthesis by expanding into the manufacture of commercial quantities of complex, next generation pharmaceuticals, sufficient for undertaking clinical trials.

In agreement with one of our key conclusions, the TCG report shows that access to significant capital is essential for developing a vibrant biotechnology industry.

Summaries of both the Ernst & Young and TCG reports can be accessed on www.industrytaskforces.govt.nz

The scale and base of innovation from which New Zealand could build new commercial capability is vital to achieving the growth targets. As an illustration of the strength that New Zealand has in biotechnology research, Appendix 1 provides a review of the established science strengths existent in New Zealand's CRIs, universities, private sector companies and research centres. In summary, New Zealand has significant strengths in large animal biology (in particular being world leading in overall knowledge of the sheep and dairy cow), as well as having world-class research teams in a number of areas of biomedical science and bio-engineering. More recently New Zealand has also emerged as world leading in some areas of enabling technology, which is technology that allows both novel and intensive data collection.

The expertise and assets that can be developed in biotechnology are:

- Long-term expertise and applied knowledge in plant and animal breeding, and genetic selection for specific traits;
- Unique germplasm and Express Sequence Tag (EST) libraries in the key species important to New Zealand;
- In depth knowledge of animal and plant physiology and metabolism;
- An understanding of proteins, carbohydrates and fats (especially in dairy) and the ability to manipulate raw materials;
- Established bioprocessing technologies and infrastructure;
- Established bioengineering skills and software design;
- Expertise in international marketing and management of both commodity and consumer food and fibre products;
- World-class biomedical research teams in niche areas of neuroscience, cardiovascular disease, asthma, diabetes, cancer, osteoporosis and bone health;
- A regulatory regime of international standard and high ethical standards;
- A high animal health status (Category 1, no history of List A (OIE) disease) for biopharmaceutical production from animals;
- The ability to plan and manage clinical trials for international studies; and
- Established R&D/industry clusters in Hamilton (dairy), Rotorua (forestry), Dunedin (biotechnology), Auckland (medical biotechnology), Palmerston North (food technology, plant sciences), Lincoln (environmental management and bioprotection/biosecurity).

This degree of strength and depth gives us particular opportunities in both ag-bio and biomedical areas in large animal-based biotechnologies, plant-based biotechnologies, biomedical science and drug discovery, bioprocessing technologies and biomanufacturing, and in innovative foods and health.

To achieve this vision several things must occur. The next section of the report outlines specific actions we think are necessary. In some we know there is more work to be done but for others we are more confident it is time to act. We identify who needs to take leadership and when. We invite Government to help industry grow this sector by indicating its support and commitment to act now.

2 A FRAMEWORK FOR ACTION

Biotechnology is fundamentally important to New Zealand. Its association with the primary sector has been the backbone of the economy. In essence, our ability to build wealth on our biological base has been the mainstay of the economy. Our biological 'knowhow' and expertise is now beginning to pervade biomedicine, industry and manufacturing, food technology and remediation of environmental damage.

Biotechnology has the potential to transform our key industries and our economy as a whole – from the steady performers of today to the stars of tomorrow.

The Action Plan

In setting the framework for action, this report has highlighted six key areas within which Government and industry need to address issues to create the environment for long-term economic and capability growth in the biotechnology sector:

- People
- Funding
- Institutions
- Infrastructure
- Regulations supporting the sector
- Global participation

Twenty-eight actions are identified. They are grouped into Immediate, – i.e. where specific activity should be initiated now; Longer Term – i.e. key underpinning activity; and Rolling which may start now but will be ongoing.

Balanced and measured development of all actions will be needed to deliver the vision of the report. Across the world, governments have recognised the importance of their role in supporting the biotechnology industry's growth. A recent report from the Massachusetts Biotechnology Council provides evidence of the continued call on government to support the sector's growth.

Therefore, the framework calls for action by both industry and Government.

2.1 People

The human element of a biotechnology industry is the most critical yet the most difficult. Talented people provide the link between research, infrastructure and funding. They hold knowledge, provide ideas and turn a great idea into a new product.

The difference between people as a resource and an essential capital resource is fundamental: a firm or a country can decide on the item required, order it, and eventually it will be made and delivered. The same set of decisions and actions may not occur so easily when it comes to acquiring a skilled workforce.

First, identifying skill requirements for both now and in the future takes time. When we consider that a workforce takes time to build, and that predictions may need to be made about educational and skill requirements 10 years hence, the task is even more difficult. This can be partly addressed by attracting overseas talent, but even then, identifying the initiatives that will either help to build the right skills at home or attract overseas workers is not simple.

These challenges are also faced by other industries. However, there are key differences in the biotechnology sector, including the long training needed for scientific and technical staff, and the fact that the global biotechnology employment market is aggressively recruiting skills in this country. This means that enduring incentives are needed to ensure New Zealand's biotechnology sector can get the right skills for its development.

The main capability gaps identified in New Zealand are:

- A continued low proportion of graduates in science, in part because science is a small proportion of the economy.
- A lack of analytical capacity in the investment community around biotechnology. Investment analysts, and the investment public at large, lack an understanding of the nature and long-term investment needs of biotechnology.
- An observed shortage of commercial experience in legal intellectual property (IP) management skills within the New Zealand legal community: Other countries (e.g. US) provide a benchmark to show how the New Zealand legal community needs to reinforce capability in this area.
- A lack of 'scientific entrepreneurs' with the ability to drive research into commercial application.
- A general shortage of generic company management capability: recruitment of world-class chief executives and managers is a barrier to growth and attraction of investment.

The first task is for the biotechnology industry to conduct further research into capability gaps. If the sector is to meet its vision and growth targets for 2013, demand for skills must be identified and the supply met by tertiary institutes and industry. We have anecdotal evidence from companies that they face difficulties in recruiting scientific and entrepreneurial talent, and that this is likely to become more difficult. The taskforce strongly recommends that the sector's future human resource needs be evaluated and measures implemented to meet future demand. We need greater understanding about the extent of shortages, their long-term effects, and likely future gaps.

Filling skill gaps will involve recruitment, repatriation and reward. To fill skill gaps, we need firstly to continue to recruit and train New Zealanders for these roles. The best students must be attracted into the sciences and this means the Government and industry working together to promote biotechnology in particular, and science generally.

Biotechnology as a career option has the advantage of being a multidisciplinary field, which may offer students more choice about where they specialise.

Next, we must recognise that part of a first-class education for a New Zealand scientist is post-doctoral work overseas. New Zealand scientists often gain commercial experience while working in international companies. So, rather than worrying about graduates leaving the country, we must focus on bringing them back, or repatriation.

To achieve that, employers here need to create work environments that encourage New Zealand scientists to return home once they have gained overseas experience. This is about providing adequate rewards, one aspect of which – the capacity to pay competitive salaries – is intrinsically linked to the growth in economic wealth that the sector can yield. Another aspect of reward is the opportunity for individuals to follow challenging career paths. We must offer opportunities.

Finally, we must promote our working environment, as well as New Zealand's expertise in certain areas, to international scientists. Attracting people to New Zealand will sometimes mean attracting world-class individuals into our businesses, universities and research institutes. For New Zealand to build up its commercial experience, recruiting overseas talent may help to build up our biotechnology sector more rapidly.

The biggest step, however, will be convincing businesses to set up here. New Zealand needs to be promoted internationally as the destination for excellent research and development. As well as employing New Zealanders, new businesses will bring talent with them, often in the areas where New Zealand is lacking. Allowing this to happen encompasses the full range of this report – from attracting funding to global participation, from our regulatory environment to our research environment and our tax rules.

There is a need for a programme addressing recruitment and repatriation of skilled people into biotechnology. Ways of doing this may include internship programmes, building on existing programmes under Technology New Zealand, repatriation schemes which tap into the World Class New Zealanders and Kiwi Expat Association (KEA) networks, mentorship initiatives, and promotion of New Zealand as a place to work to international scientists, entrepreneurs and business leaders. Recruitment of patent attorneys, where companies second patent attorneys from the US to work alongside New Zealand scientists and patent attorneys, is an example of such an initiative currently underway.

CASE STUDY

John Bedbrook – World Class New Zealander

Industry New Zealand's World Class New Zealanders (WCNZ) programme is focused on increasing the international competitiveness of New Zealand businesses and sectors by improving their global connectedness.

In March 2003, WCNZ brought to New Zealand expat Dr John Bedbrook, an international expert on agricultural biotechnology and president and chief executive of US biotech company Verdia.

During his visit he met with local biotech companies, Crown Research Institutes, universities, biotech organisations and Ministers.

He provided valuable information on global trends, strategic advice, feedback, contacts and an assessment of New Zealand's biotech potential from a global perspective.

"Being successful is essentially about having a point of difference and selling that difference," he says. "It's important to get out and participate in the global market-place, to feel it and understand it."

There is a need for our education system and broader government to address the integration of legal, scientific and commercial disciplines in degree structures.

The most difficult areas in which to develop skills are, not surprisingly, the ones where people are most needed. Entrepreneurs have a different skill set from their scientist colleagues, made up of talents that cannot be learnt in a classroom or academic environment – although they may be nurtured. Entrepreneurship is driven by curiosity or is learnt in the commercial environment. The key is to identify entrepreneurs early in their careers and foster their flair and creativity, at the same time providing tools to make the business side easier. One avenue is through hands-on commercial experience in a large biotechnology or pharmaceutical company.

	Recommended Actions	Responsibility	Timeframe
Action 1	That industry, with Government, define a programme for targeting the recruitment and repatriation to New Zealand of five key scientists and entrepreneurs (i.e. 'rainmakers') per annum with the skills and experience to establish new and innovative research labs within an effective commercialisation structure. This may include working with programmes such as World Class New Zealanders and the Kiwi Expat Association as a way to attract talent.	Government (Industry New Zealand) Industry	Immediate action
Action 2	That industry, with support from Government, performs a capability analysis drawing on the suite of audits in existence (e.g. Biotenz capability audit) to identify gaps in skill sets. This analysis should include recommendations on how to engage with the education sector to develop programmes to bridge the identified gaps.	Industry and Government (Ministry of Research, Science and Technology, Tertiary Education Commission, Industry New Zealand)	Rolling action

2.2 Funding

Most research funding for the biotechnology sector currently comes from the Government with a total spend on modern biotechnology and biotechnology-related research in 2002 of approximately NZ$134.5 million across the three funding agencies of Foundation for Research Science and Technology (FRST), Health Research Council (HRC) and the Royal Society of New Zealand. It is important that this funding is treated as an investment for the future and not a cost. Government needs to continue to support basic research, which may not result in direct or realisable gains for industry, and to increase this support to an optimal level. However, industry also has a role to play in engaging at this end of the research spectrum. To maximise the potential of the research coming through, industry must increase its investment in developmental and applied research. Successful investment in biotechnology now will attract more investors in future, and breed further successes.

2.2.1 Research capability

Basic research forms the starting point for biotechnology developments internationally. The bulk of funding for basic biotechnology research in New Zealand is sourced from the Government's Marsden, Research for Industry and New Economy Research Funds. This research underpins new knowledge and contributes to the development of researchers. The Health Research Council also funds biotechnology research through the Public Good Health Research Fund.

Funding in these is heavily oversubscribed with, for example, an approved success rate for proposals to the Marsden Fund of only 10 percent. Discussions with overseas counterparts suggest there should be an approved success rate of no less than 30 percent overall to ensure that the best ideas continue coming forward and we retain young and mid-career researchers.

To this end, we recommend that the overall investment in biotechnology research through schemes including the Marsden, NERF, Health Research and Research for Industry funds continue to increase from the current level of $134.5 million to $300 million over the next five years. While Government is likely to continue to be a major funder of basic research, industry should also look at how it can support basic research.

	Recommended Actions	Responsibility	Timeframe
Action 3	That investment in biotechnology research continues to grow to a level of $300m pa over the next five years. Industry to explore mechanisms for the provision of strategic co-funding in basic biotechnology research.	Government (Ministry of Research, Science and Technology) Industry	Long-term action

2.2.2 Investment along the R&D spectrum

Growth in biotechnology is borderless. Access to capital is a critical driver behind the strategic alliances, mergers and acquisitions, and spin-offs currently being witnessed in the biotechnology sector.

At the various stages of business growth, biotechnology firms require different types of funding and support. Basic and applied research funding allows research organisations to develop new ideas. At the development stage, start-up companies require support to develop ideas into new products. At the commercialisation stage, support involves helping these small concerns to grow business.

Each stage of development – from research through to commercialisation – entails different types and levels of risk and uncertainty. For instance, a firm in the research stage will face different potential roadblocks than one at the product testing stage. Funding may be required from various sources for activities including research, proof-of-concept, product testing, field and clinical trials, manufacture, marketing and distribution. A clear and well-managed process to proactively lead research and innovation to commercialisation is essential given the extended timeframes that operate over this process in the biotechnology sector.

Furthermore, risk profiles attached to the various stages of development are not the same in the different sub-sectors in biotechnology – a company manufacturing and testing drug delivery systems faces different challenges than one developing and testing the drugs themselves.

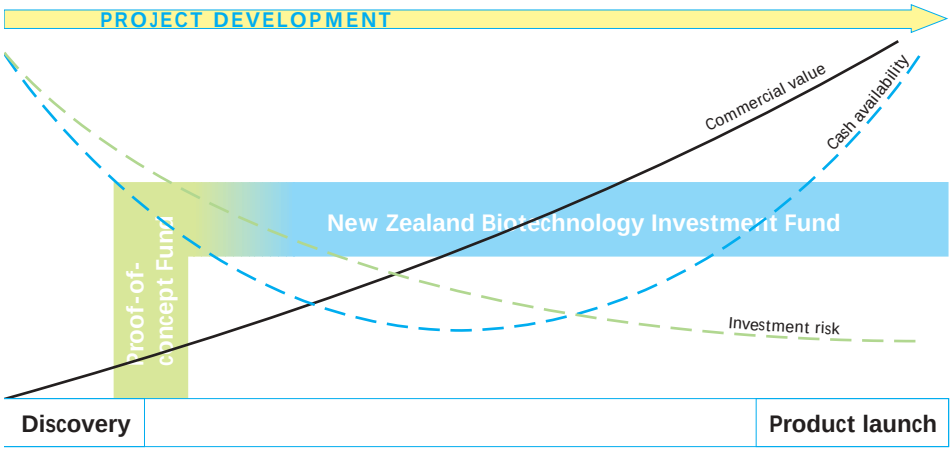


Figure 3 – Risk Profile R&D to Commercialisation

CASE STUDY | **Antipodean Biotechnology Ltd** – Government funding

In November 2002, Technology New Zealand announced a $1.7 million grant – its biggest ever research and development grant – to Antipodean Biotechnology Ltd which is developing a new chemical entity, mitoquinone, as a treatment for Friedreich's Ataxia and Huntington's disease.

Antipodean is a seed venture capital company set up to fund the development and commercialisation of new drugs discovered in New Zealand, using New Zealand expertise and facilities. The company is working with seven of New Zealand's leading research institutes.

The Technology New Zealand funding, which has been matched dollar-for-dollar by Antipodean, was crucial in keeping the mitoquinone project in New Zealand. The project is groundbreaking because it is the first time a drug discovered in New Zealand will be manufactured, formulated into tablets, tested for absorption, metabolism and safety before proceeding to the first patient studies, all within New Zealand.

Meeting the variety of demands of the sector requires flexibility. Having too many separate funds aimed at different stages of product development can mean that firms miss out if their problem does not quite fit the criteria for the fund (or funds) they apply to. A Biotechnology Investment Fund that can match funding solutions to individual requirements would ensure that worthy firms will not miss out on support where it is critical. We perceive benefit in reviewing the operation of existing overseas funds such as the Australian Biotechnology Innovation Fund (BIF). By operating 'horizontally' along the research spectrum and providing different types of support – e.g. grants, suspensory loans, loans, venture capital, private equity, public financing etc – such a fund would be able to meet the needs of the sector appropriately.

Investment in biotechnology throughout all its phases, from research to manufacture and marketing, is at the higher end of the risk spectrum. An investment fund of the kind proposed needs to reflect this reality, and that it will attract its funds from a variety of sources which are prepared to dedicate a small proportion of their investment funds into higher risk opportunities. It will be important to investors in a biotechnology investment fund that they are sharing the risks with like investors, and that the biotechnology investment fund has scientific evaluation capability as well as financial expertise to ensure risks are well measured, and the investments well placed.

On this basis, the taskforce would see the proposed fund being supported by major financial investors, including the New Zealand Government and private sector investment funds, as well as private equity sources. We anticipate that to have a real impact, the fund would need to be at least about $200 million, and that Government may be required to invest up to 25 percent of this amount. This could include any unspent capital in the Venture Investment Fund. The taskforce realises that if it is to make an investment of this size, the Government will expect to be heavily involved in setting up the fund. The taskforce would expect a fund that is well supported within New Zealand also to attract overseas investment capital. The proposed fund therefore extends beyond the conventional concept of a venture capital fund, but something of this scale and breadth is essential to the development of the biotechnology industry in New Zealand.

As well as supporting the growth and development of individual firms, such a fund will aid the development of the biotechnology sector as a whole. Better support for firms will lead to better support to individuals, the improvement of infrastructure for the industry, more extensive global participation of New Zealand's industry and improved performance of institutions. These issues are discussed in more detail within this report.

Finally, as an initial step, there is a critical gap in the funding currently available, which the Government should address immediately. The establishment of a 'vertical' biotechnology proof-of-concept fund, to enable researchers to test the potential of turning an idea into a product, should happen as soon as possible.

	Recommended Actions	Responsibility	Timeframe
Action 4	That industry and Government establish a horizontal Biotechnology Investment Fund in the order of $200m to stimulate the commercial development of viable biotechnology research and to encourage growth in new companies.	Industry Government (Industry New Zealand, Ministry of Research, Science and Technology)	Immediate action
Action 5	That Government establishes a vertical biotechnology proof-of-concept fund to stimulate the pull-through of basic research.	Government (Ministry of Research, Science and Technology)	Immediate action

2.2.3 Tax

In many countries the tax system is used as a vehicle for providing various forms of support for sectors identified by their governments as requiring special promotion. The research undertaken by Ernst & Young into the biotechnology sectors of seven countries comparable to New Zealand lists some of the financial and fiscal measures offered by these countries.

The taskforce has identified a number of tax measures that would facilitate the commercialisation of biotechnology, and has been able to discuss these with representatives of the Inland Revenue Department and The Treasury. A number of the specific points raised are already being studied by officials.

The taskforce's principal recommendation is that the Government should not only complete this work, but also undertake a broader study of what tax structure could be introduced that would be most appropriate for this country's biotechnology sector. The study would take into account the sector's defining characteristics of heavy investment in front-end research, high risk and high costs, and the long lead times from basic research to a commercial return. A similarity between biotechnology and petroleum exploration is noted, and that certain provisions specific to the petroleum industry have been in the tax structure for some time.

The tax structure study should encompass the following issues:

Employee share options which represent one of the few ways cash-strapped research enterprises can provide scientists with a financial reward in the event that their research is, ultimately, successfully commercialised. The tax impost on the capital appreciation of options, and the volatility of an enterprise's value during commercialisation, can compromise the ultimate reward, however. There are ways of avoiding the tax impost, but these are complex and a distraction for research companies. A more straightforward tax regime for share-based rewards for high-tech employees should be developed.

Continuity rules for tax losses which mean that changes in ownership structures resulting from successive injections of new capital can result in the forfeiture of carried forward tax losses. Current continuity rules should be reviewed.

Structures for allowing early tax losses to accrue to investors: Corporate structures such as unincorporated joint ventures and limited liability partnerships allow the benefit of tax losses incurred during the research and development phases of a biotechnology initiative to accrue to the investors supporting the initiative, thus providing them with a small benefit during the lengthy period before the initiative becomes revenue generating. However, these structures can be complex for both the venture and its investors, and can create problems for the ultimate structure for commercialising the research. Work needs to go into developing a straightforward structure so those who provide investment support for research and development receive the benefit of tax losses.

Taxation of technology transfer concerning issues relating to the taxation and tax deductibility of technology transfers, in particular where the technology being transferred has some value in terms of the research it represents, but has no commercial value based on earnings.

	Recommended Actions	Responsibility	Timeframe
Action 6	Government to undertake a broader study of the tax structure applicable to the New Zealand biotechnology sector, taking into account its particular characteristics of heavy front-end research costs and long lead times to commercialisation.	Government (Inland Revenue Department, The Treasury)	Rolling action

2.3 Institutions

Certain institutions within New Zealand's biotechnology sector require extra attention if the industry is to grow. CRIs and tertiary education providers play a critical role in the generation of new ideas, and their role must be well defined and supported by industry and government. Further, the pharmaceutical industry will play a major contributing role to biotechnology in New Zealand and this relationship must be fostered.

2.3.1 Public institutions

The bulk of biotechnology research funding in New Zealand goes to CRIs and tertiary education providers which are, therefore, depositories and generators of essential knowledge and understanding.

However, these institutions are not always the right place for new ideas to be developed into new products. In some cases, New Zealand would benefit more if CRIs and tertiary providers were able to 'let go' and provide more opportunities for the private sector to commercialise research, rather than competing with them. Increasing the opportunities available to New Zealand companies to take a product to market is crucial to the maturation and ongoing success of the sector. This will require CRIs and the private sector to also consider broad issues like IP management, as well as the specifics of the industry and what drives the commercial biotechnology market.

Over the past two years the Government has clarified its expectations of CRIs regarding commercialisation. Specifically, it has told CRIs to keep improving their ability to commercialise research and to look to doing this through partnerships, either with each other, or with other public and private sector players. We endorse this direction and recommend that CRIs and tertiary education institutions also focus on opportunities to create stand-alone businesses through spin-out of commercially viable research. We also recommend that industry continue to proactively partner and invest with CRIs to extract utmost commercial value from their ideas.

Finally, we recommend that CRIs and tertiary providers explore how researchers may take their ideas into a new business and return to their institution once the commercialisation of the research has embedded, if they so choose.

	Recommended Actions	Responsibility	Timeframe
Action 7	That industry, Crown Research Institutes and tertiary education providers develop a best practice programme covering the interface between industry–science. This programme should aim to stimulate market-led biotechnology research within a framework that recognises: ■ The mutual benefits of industry–science partnership; ■ The need for open and effective management of IP; ■ Opportunities for research teams to gain an insight on drivers within the commercial biotechnology market; ■ Proactive investment by industry to extract greatest possible commercial value from biotechnology research; and ■ The role of Government in monitoring its expectations of Crown Research Institutes to commercialise research output.	Industry, Government (Crown Research Institutes, tertiary education institutions)	Long-term action
Action 8	That Government reinforces its expectations of Crown Research Institutes and tertiary education institutions to spin-out commercially viable research into stand-alone businesses.	Government (Crown Company Monitoring Advisory Unit, Tertiary Education Commission)	Immediate action

2.3.2 The pharmaceutical sector – why is it important?

The pharmaceutical industry is one of the largest private research and development investors in the world, investing approximately US$36 billion annually in R&D. For biotechnology companies developing biomedical products, pharmaceutical companies are major sources of investment funds. The importance of pharmaceutical companies to biotechnology companies comes down to:

- The magnitude of the R&D investment;
- Biomedical research supporting the development of pre-clinical and clinical trials; and
- A capacity to get products internationally registered and on the market.

While biotechnology firms need pharmaceutical companies' input in the later stages of product development (trials through to marketing), pharmaceutical companies themselves have preferred to invest in new ideas earlier on, during research. The pharmaceutical influence is, therefore, important at all stages.

In New Zealand currently, tensions between government and pharmaceutical companies are inhibiting biotechnologists wanting to establish and continue their links with pharmaceutical companies. The main source of this tension appears to be that, while the Government may have a range of work relevant to the pharmaceutical industry (for instance, through policies on economic development, research and health), the only formal interaction is through PHARMAC. But the Government's policy of securing pharmaceutical needs at lowest cost through PHARMAC is only one area in which there should be a relationship between the Government and pharmaceutical firms. Formal coordination in addition to PHARMAC, will help ensure that the range of issues and interactions between the pharmaceutical industry and the Government are viewed together, not in isolation.

Given the right policy environment and partnership between government and industry, we believe significant and rapid progress can be made toward reversing the trend for companies to discontinue their research efforts in New Zealand. In general, the Government, PHARMAC and the pharmaceutical industry must find ways to address not only the Government's concern to manage pharmaceutical costs, but also provide a framework within which members of the industry can see themselves as long-term contributors to the development of New Zealand biomedical research.

Practical steps parties might take to relieve the tension include:

- Introducing some certainty and predictability into PHARMAC's funding by replacing year-to-year funding with three-year rolling plans.
- Developing an action agenda for the industry. The Researched Medicines Industry Association of New Zealand (RMIANZ) has started the ball rolling with their report "Bio-Pharmaceuticals – A Pathway to Economic Growth".

	Recommended Actions	Responsibility	Timeframe
Action 9	That Government takes steps to reinforce the relationship with the pharmaceutical industry to stimulate research investment. These steps will include: ■ Introducing certainty and predictability into PHARMAC's funding, by setting ongoing three-year rather than year-to-year funding; ■ Developing an action agenda for the industry, building on the RMIANZ report "Bio-Pharmaceuticals – A Pathway to Economic Growth"; and ■ Reviewing the channels through which Government engages with the pharmaceutical industry.	Government (Ministry of Economic Development, Ministry of Research, Science and Technology, The Treasury, Industry New Zealand, Ministry of Health), Industry	Immediate action

2.4 Infrastructure

2.4.1 Industry networks

The exchange of ideas and information between companies is critical to the growth of the biotechnology sector. New Zealand is a small country and if we use our internal and formal networks well then we can respond quickly and effectively to opportunities and challenges presented by the fast changing global scene.

Several significant projects have helped develop networks over the past 18 months, for instance Biotenz's development of a strategy for the biotechnology sector, and Industry New Zealand's work in initiating the Biosphere website. But the industry must now take stronger leadership in consolidating these efforts. We call for the development of a single integrated industry body which will be able to focus its energy on building the whole sector, not just parts of it. We recommend that Government provide seed funding for this new body, with the recognition that it will become self-sustaining after a period of three years. This body could take over responsibility, when appropriate, for the various sector support initiatives now run by government (e.g. Biosphere brand, cluster development, training packages).

	Recommended Actions	Responsibility	Timeframe
Action 10	That industry consolidates its networks, and focuses the efforts of existing networks such as Biotenz, the Biotechnology Association, BioSouth and Bio Auckland, to create one strong industry body with sufficient funds to augment the whole sector. Consolidation should address: ■ The development of a strategic plan to concentrate infrastructure and research investment in key biotechnology areas; ■ The facilitation of partnerships between the primary sector, research institutions and feeder industries; ■ Continuation of the development and building of new clusters and communities; and ■ Progressing existing Government-led sector support projects.	Industry	Long-term action
Action 11	That Government supports the establishment of a single biotechnology industry body through providing seed funding of $450,000 per year for the next three years.	Government (Industry New Zealand)	

2.4.2 Physical infrastructure

(i) Clustering around existing strengths

For the biotechnology industry to thrive, we must identify our strengths and develop clear strategies to build on them – and support the institutions and infrastructure that exist in those areas.

New Zealand's foremost comparative advantage in biotechnology is in its primary production industries and unique biological base. The main focus of the investment in biotechnology in the primary industries centres on the goals of improving productivity, adding value to the resource and diversifying the products, processes and services that we generate into higher value areas.

Other areas we can be competitive in include:

- Biomedical research at Otago and Auckland universities;
- Animal-based and forestry research – centred at the Ruakura Campus in Waikato, Palmerston North (Massey University, CRIs and Fonterra Research Centre), and Forest Research in Rotorua;
- Plant science at HortResearch, AgResearch, Crop and Food, Forest Research, and at Massey and Lincoln universities;
- Environmental management biotechnology; and
- The marine cluster in Nelson.

We should promote clusters with existing strengths. People and partnerships will be the key to new growth and development. The establishment of co-funded R&D schemes, research consortia and Centres of Research Excellence are a signal of the Government's commitment in this area. Industry has also seen the benefits, and both companies and primary sector groups have increased their investment in research and development. This has led to key partnerships in areas of sheep genomics, functional foods, drug discovery and natural products.

Augmenting these initiatives through investment in physical infrastructure – for instance, by establishing fully compliant sites, such as technology parks – will show the country's commitment to biotechnology and science in general. We advocate the implementation of a dedicated 'Request for Interest' (RFI) to determine what infrastructural capacity building is required, to identify gaps, and to determine how to build stronger linkages through coordination of infrastructure capacity. An RFI would also help offset withdrawal of funding in this area by the Wellcome Trust and can be expected to lead to a requirement for an infrastructure development fund.

(ii) Platform technologies

Platform technologies are underpinning generic capabilities (skills, resources, and infrastructure) that allow a number of applications to build off them. In biotechnology these include the 'omics' areas of genomics, proteomics and metabolomics, but also bioinformatics and reproductive technologies (including transgenics and cloning).

Because New Zealand is small, there are challenges to planning and funding new skills, capital items and major infrastructure development. Most companies and research institutions are not able financially to buy large capital items, and have difficulty funding and upgrading these through depreciation, especially for equipment where there is a high rate of obsolescence.

In acquiring specialist equipment and developing research capability, duplication in different institutions is neither sensible nor necessary. The same can be said of allowing capability and capacity that is essential to the industry's future to be captured by one player.

A more strategic approach is needed while the sector is growing. Planning for infrastructure and capability development needs to be identified and made a priority. In addition, mechanisms for developing a 'New Zealand Inc.' approach are needed in areas of large assets or platform technologies. This strategic forethought must identify opportunities for attaining critical mass in research capability (as discussed earlier) as well as through partnerships, collaborations and mergers of existing teams and organisations.

(iii) Link with Information and Communications Technology (ICT)

Information technology is an essential requirement for modern biotechnology, and we must work with the ICT industry to ensure we are moving in the right direction, especially in the areas of data management and processing.

In particular, high-speed/high-bandwidth networking, the development of overall computing capacity for the future, and bioinformatics have been identified as important for both biotechnology research and the industry. The private sector and research

organisations have been moving ahead in these areas, but they would benefit from better coordination, support and resources to ensure they are set up with the right intent for the country as a whole.

Bioinformatics remains a crucial tool for modern biotechnology. Access to public international bioinformatics databases that store DNA sequence data, protein structure and functional domain profiles, is an ongoing and rising cost. Industry and Government need to consider initiatives and funding mechanisms for options such as setting up a mirror website of these databases so that New Zealand organisations can retrieve data without incurring international traffic charges.

New Zealand needs to catch up quickly with other countries in developing high-speed networking and Internet 2. The Next Generation Internet Consortium has formed to take this forward, but this is a national imperative requiring both public and private sector support. This is a critical enabling infrastructure for biotechnological and medical advancements.

Another area strongly related to people skills is the establishment of world-class biotechnology education programmes and modules building on state-of-the-art visualisation and learning techniques being developed within the ICT community.

	Recommended Actions	Responsibility	Timeframe
Action 12	That Government coordinates a programme to identify large asset platform technology gaps, and mechanisms to fund those. This should include the implementation of a dedicated 'Request for Interest' to determine what infrastructural capacity building is required.	Government (Industry New Zealand, Ministry of Economic Development, Ministry of Research, Science and Technology, Foundation for Research, Science and Technology)	Immediate action
Action 13	That industry works with all education providers to develop a world-class suite of biotechnology education programmes building on state-of-the-art visualisation and learning techniques.	Industry	Long-term action

2.4.3 Support from the community

The Biotechnology Strategy Discussion Document released in October 2002 aims to "Build understanding and constructive engagement between the community and the biotechnology sector". This stems from the idea that a well-functioning society balances social, economic and environmental considerations.

We endorse this view, and believe the biotechnology industry will be strengthened if research and development works in partnership with and gets support from society

generally. To achieve informed decisions, consumers and the community need information and opportunities to:

- Understand and assess benefits and risks associated with particular technologies;
- Have confidence in regulatory mechanisms; and
- Have the chance to influence policy.

Work can also be done to demonstrate the huge benefits biotechnology offers in such areas as human health, agriculture, and the marine and forestry industries.

We recognise ongoing concerns within parts of the community about genetic modification (GM). We must build understanding within the New Zealand society about the huge spectrum covered by biotechnology within life science. This will help to ensure the debate about GM relates to the part of the spectrum that the technology occupies. The taskforce has noted the responsive and open debate that has taken place through the Royal Commission on Genetic Modification process, and welcomed the level of public consultation that process has ensured.

Within the sector also, there are different groups who may have different perspectives on certain issues. The industry as a whole will succeed if those diverse perspectives are not only respected but also used and integrated into thinking about the sector's development.

For example, as tangata whenua, Maori have a major interest in the primary sector through land-based industries, fisheries, and forestry – as does the biotechnology industry. Both Maori and the biotechnology industry can gain by working together as the sector develops. Both groups also have a lot to lose if Maori do not participate in growth of the industry. For this reason, Maori – through regional, industrial and government authorities – are one group from whom the industry should seek explicit and ongoing support.

	Recommended Actions	Responsibility	Timeframe
Action 14	That industry works with Government on the goal of 'building understanding and positive engagement between the broader community and the biotechnology sector'. This should result in projects that: ■ Recognise the value of different perspectives on growth of the sector; ■ Gain support, including from appropriate Maori authorities; and ■ Cultivate effective and innovative education programmes to communicate the cultural, economic and environmental benefits which the application of biotechnology can achieve.	Industry and education providers	Long-term action

2.5 Regulations that support the sector

In the final chapter of its report, the Royal Commission on Genetic Modification dubbed the 21st century the biotechnology century. The themes of 'preserving opportunities' and embracing biotechnology, but with care, were evident. We echo this view.

In formulating its recommendations, the Royal Commission carefully considered a range of evidence and viewpoints. We believe the Royal Commission got it right and believe a balanced approach is appropriate for building the biotechnology sector. New Zealand's competitive advantage is in our existing biological base and primary sectors. Economically, we cannot afford to turn our backs on the opportunities biotechnology offers.

The Royal Commission's inquiry considered in detail the existing institutional structures and regulatory framework for managing genetic modification and wider biotechnology applications. Apart from some minor enhancements, all were considered sound. We concur with the Royal Commission's overall view, but believe there are still regulatory issues that need addressing. These are outlined further below.

2.5.1 Our complex regulatory environment

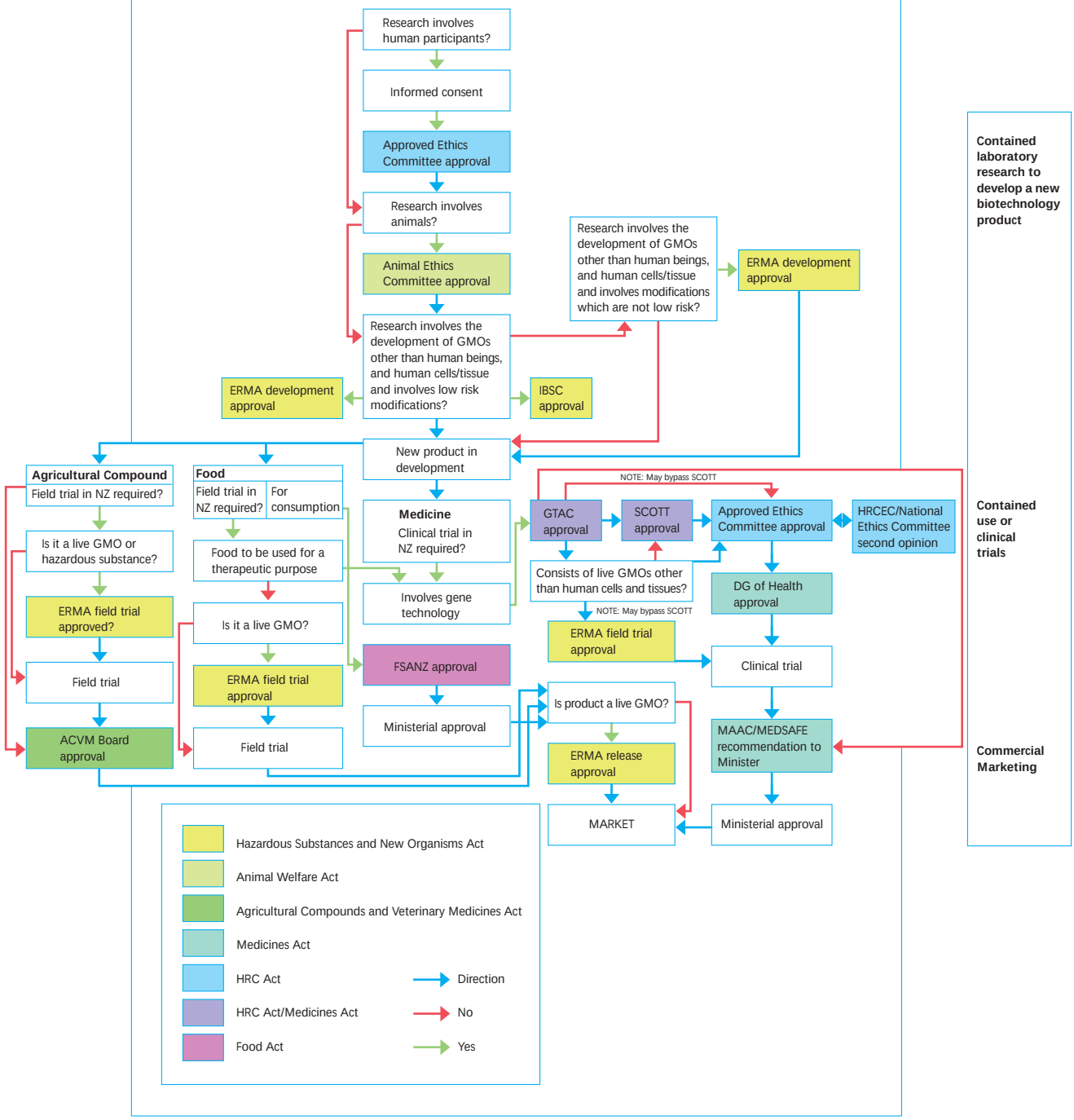
Regulations are key in terms of balancing innovation while safeguarding human health and the environment. As an industry and nation, we need to act responsibly in meeting society's safety and ethical concerns. Among developed countries, New Zealand's regulatory system for approving new biotechnology products is recognised as being at the highest international standard. It is in our trading interest to maintain this standard.

However, compliance costs associated with some aspects of the regulatory system are excessive. The diagram overleaf is based on one that appeared in the New Zealand Biotechnology Strategy Public Discussion Paper and shows the hoops a firm can face to gain approval for a new biotechnology product.

This complexity alone, without the problems that exist in relation to certain areas (i.e. the administration of the Hazardous Substances and New Organisms (HSNO) Act) can inflict huge costs and delays on biotechnology firms. Our major conclusion in this regulatory minefield is that a two-yearly review should be undertaken into the compliance costs of doing biotechnology in New Zealand. Such an audit would consider how, practically, the HSNO, Medicines and Agricultural Compounds and Veterinary Medicines (ACVM) Acts allow companies and researchers to operate. Our advice is that the audit be carried out independently of government. It must have a strong affinity for the commercial drivers and operating environment of industry.

This needs to be closely linked with the speeding up of any regulatory reform; if a simple legislative change is identified, the Government should commit to making the change within a year. At present, law changes are onerously expensive and time-consuming. A guide to the regulatory framework for approving new biotechnology products could also be developed and updated alongside the regular review.

Figure 4 The Current Regulatory Framework for Approving New Biotechnology Products



New Zealand needs to move compatibly with its major trading partners to ensure the regulatory system meets international standards and is competitive. This translates into greater regulatory harmonisation in areas such as medicine approval, complementary health care and patent protection. A move to establish a single Trans-Tasman Therapeutic Goods Regulator is an example.

Research and industry should strive to adopt the US Federal Drug Administration (FDA) accreditation standards when undertaking research and clinical trials. Market research has indicated that the FDA is one of the most trusted organisations in the US. By aspiring to FDA standards, the New Zealand biotechnology sector is adopting world-best practice. Close attention must, nevertheless, also be paid to the international debate on these standards through bodies such as the International Conference on Harmonisation.

	Recommended Actions	Responsibility	Timeframe
Action 15	Government to undertake a biennial review of the compliance costs associated with biotechnology, bearing in mind the processes required to accelerate any regulatory reform identified.	Government (Ministry of Economic Development)	Rolling action
Action 16	In establishing a standards framework for research and clinical trials, the research community and industry should: ■ Strive to adopt FDA accredited standards for research and clinical trials; and ■ Seek ways to engage in the debate in wider international standards bodies such as the International Conference on Harmonisation (ICH).	Industry	Long-term action

2.5.2 The Hazardous Substances and New Organisms (HSNO) Act

The agribusiness and research community often remark on unwieldy consultation processes and uncertain timeframes associated with the Hazardous Substances and New Organisms (HSNO) Act. In some cases there is duplication. For example, live new organism medicines currently require dual approval under the HSNO and the Medicines Act. Compliance issues have also been raised in the medical area and generally relate to multiple ethics approval processes.

There is an urgent need, however, to address the role and operations (including cost apportionment of approvals) of the Environmental Risk Management Authority (ERMA) in its consideration of applications under the HSNO Act. This is specially so where submissions on an application from the public are such that ERMA determines that there should be a hearing.

The taskforce believes ERMA's role as a quasi-judicial regulatory authority should be reinforced. Thus, while ERMA should continue to receive and consider public submissions, it should be made clear that it is not holding a public inquiry, and that submissions should be

focused on the specifics of individual applications. While it is appreciated that ERMA has not wanted to further extend its hearings by providing for cross-examination, hearing procedures should be tightened to require submitters to adhere to normal rules of evidence and to support statements with relevant authority. This may circumscribe submissions which address religious, spiritual and cultural concerns, but these are matters which may now more appropriately be dealt with through the recently established Bioethics Council.

We also need to ensure that implementation of HSNO reflects internationally competitive best practice in a number of specific areas including, for example, the growth of GM micro-organisms under approval in containment vessels and other broader areas such as exemption thresholds for the sale of certain biotechnology chemical materials for research and experimental use.

	Recommended Actions	Responsibility	Timeframe
Action 17	That a review be undertaken to ensure that streamlined and coordinated regulation practices operate under the HSNO, ACVM and Medicines Acts to avoid duplication.	Government (Ministry of Research, Science and Technology)	Rolling action
Action 18	That the following changes be made to the ERMA hearings and HSNO Act approval processes to ensure New Zealand has a world-class regulatory system that meets environmental protection requirements and is quick and cost efficient: ■ ERMA to adopt stricter compliance with rules of evidence procedures within its hearing process; ■ Channel all generic submissions not specifically related to an application for HSNO Act approval through an appropriate ethics council (e.g. bioethics) on the basis that a mechanism should be in place to ensure all year-round response; and ■ Adopt a more balanced cost recovery practice in the operation of the approval process.	Government (Ministry of Research, Science and Technology)	Immediate action
Action 19	That Government amends the current HSNO regulations relating to: ■ The growth of GM micro-organisms in containment vessels, to bring it into line with Australian legislation; and ■ Containment approval for small quantities of chemicals sold for research use, by broadening the exemption for experimental or research use of such materials, to bring it in line with US practice.	Government (Ministry of Research, Science and Technology)	Immediate action

2.5.3 Intellectual property (IP)

Getting intellectual property law and practice right is crucial if New Zealand is to be competitive internationally. Historically, New Zealand has been a net importer of intellectual property – a successful biotechnology industry will require New Zealand to become a net exporter. Intellectual property laws must reflect this evolving perspective. Government has been too slow at dealing with IP law issues, to the point that this country is falling behind its competitors in the innovation race. The Government needs to start dealing with these regulatory issues. Firms and research organisations also need to develop sound IP practices to ensure that new ideas are protected.

Intellectual property legislation

If New Zealand is to have flourishing biotechnology, agri-biotechnology and pharmaceutical sectors, it must have in place modern IP laws and bring regulations into harmony with our international partners.

The biotechnology industry – especially pharmaceutical products – face long lead times in product development. First patenting to final regulatory approval may take more than 12 years. This means that the effective patent life of the product – the period during which the patent owner is the sole seller – is considerably shortened in some cases.

In 1995, New Zealand extended the patent term to 20 years across the board, while at the same time repealing provisions for extending patent terms beyond this. In some countries, the patent term for some products (usually pharmaceuticals) can be extended to take account of the portion of the patent term lost while carrying out the tests and trials required to gain marketing approval. The absence here of the provision to extend patent terms is a disincentive for major pharmaceutical firms to invest.

Pre-expiry testing is a related matter that is particularly important for pharmaceutical products. Upon expiry of a patent for pharmaceuticals, generic products may enter the market. Generic pharmaceuticals must obtain approval from the Minister of Health before they can be marketed in New Zealand. Pre-expiry testing allows the generic pharmaceutical to enter the market promptly after the patent on the original pharmaceutical expires.

The taskforce is concerned that New Zealand's patent law relating to biopharmaceuticals is considerably less favourable for biotechnologists than the laws of other OECD nations. In particular, New Zealand patent law is unique in that it contains the newly enacted pre-expiry testing provision in the absence of a 15-year effective patent life for biopharmaceuticals. As far as the taskforce is aware no other OECD nation has this combination of provisions. The solution – which will send immediate and positive signals to foreign investors – is to harmonise New Zealand law with other OECD nations by adopting a 15-year effective patent life.

Plant variety rights is another specific area where New Zealand needs to catch up with its competitors. In its response to the report of the Royal Commission on Genetic Modification, the Government has agreed to amend the Plant Variety Rights Act 1987 to bring it into line with the 1991 international convention known as the Union for the Protection of New

Varieties of Plants (UPOV) 1991 (although actual ratification is not required). This amendment is urgently required as the present legislation means that breeders cannot get protection for essentially derived plant varieties. In other words, anyone can breed and sell a new variety of plant derived from the protected variety and not have to pay a royalty. Growers can also save seed from a protected variety and subsequently plant it without paying a royalty. Effective plant variety protection is a crucial incentive to ongoing R&D investment and an essential means of guaranteeing a return on investment. While these issues are currently under review, expediting these plant variety rights reforms is important.

Added to all these specific issues is the fact that regulatory change occurs very slowly in New Zealand. The current review of the Patents Act has been in train for at least three years with no end in sight. While there are some issues that do require more time and caution, we believe the Government should institute a fast-tracking process in order to effect less contentious changes more quickly.

Intellectual property practice

Sound intellectual property practices are critical for researchers and managers. The industry could benefit significantly if it instigated the following initiatives:

- A best practice biotechnology IP management manual; and
- Intensive workshops and training in biotechnology IP management.

Biotechnology Australia has developed a comprehensive IP manual for biotechnology. It recognised the need to gain maximum benefit from its investment in research through the creation, protection and exploitation of biotechnology related intellectual property. This manual would provide an ideal template from which to build a New Zealand supplement.

	Recommended Actions	Responsibility	Timeframe
Action 20	That Government amends patent legislation to accommodate biotechnology product development times so that the effective patent life is extended and New Zealand is in line with international best practice.	Government (Ministry of Economic Development)	Immediate action
Action 21	That the Government amends the New Zealand Plant Variety Rights Act 1987 to introduce the concept of essential derivation.	Government (Ministry of Economic Development)	Immediate action
Action 22	That Industry New Zealand, in partnership with industry leaders and Biotechnology Australia, develop an IP management manual specifically for biotechnology.	Government (Industry New Zealand) Industry	Immediate action
Action 23	That industry facilitates regular biotechnology IP management training workshops to develop intellectual property knowledge in New Zealand.	Industry Government (Industry New Zealand)	Rolling action

2.6 Global Participation

The global environment in which biotechnology operates has no borders. Capital, people and technology flow freely. Most countries are focusing on biotechnology as a key sector for their future economic growth. New Zealand must be constantly reminding the rest of the world of our openness to the biotechnology industry and letting the rest of the world know what our niche capabilities are. In particular, we must seek to develop international networks that will be vital to our economic growth. Such networks will enable us to explore joint venture opportunities and form international license agreements on our IP. We are calling on industry, research providers and government alike to substantially shift our focus in the biotechnology sector to enable New Zealand to engage effectively in global biotechnology markets.

Effectively promoting New Zealand biotechnology requires the involvement of both government and industry. We want the rest of the world to know that New Zealand has a world-class biotechnology sector, with expertise in the primary sector and in applying biotechnology discoveries.

Effective branding will help us attract more overseas investment and talent. In turn, international partnerships and joint ventures will strengthen opportunities to grow New Zealand's biotechnology sector. Intellectual property skills and commercial acumen will also become more sophisticated. The result will be a vibrant biotechnology sector that has a New Zealand flavour and is of national benefit.

The BiosphereNZ website set up by Industry New Zealand, the recent Pacific Rim Biotechnology Conference and attendance at Bio2002 were all good starts at promoting New Zealand internationally. This taskforce recommends that efforts continue to be made to set up international contacts, including having a stronger presence at international fora and holding more high-level meetings in New Zealand.

CASE STUDY | **Biosphere New Zealand** – world-wide spread

BiosphereNZ was launched by the New Zealand biotech industry in November 2002 to increase global awareness of New Zealand's biotechnology sector and market its success to international investors and researchers.

The website – www.BiosphereNZ.com – contains significant information on biotechnology businesses, industry organisations and research institutes.

"Both industry and government recognise the need for more investment and better coordination of resources and knowledge for that growth to continue," says Peter Lennox, Director Biotechnology at Industry New Zealand.

More specifically, New Zealand must also take a more focused approach when it comes to how we work with major players and our major trading partners. It may be useful to develop country-specific partnerships with countries including Australia, Singapore and parts of the US. The key will be identifying countries with which we are not competing directly, and forming relationships that benefit both. We may need to look hard at how we establish partnerships at the individual company level. Business partners may not be in the classical biotechnology sector, but may be companies who can add value in the delivery of products and services to the market. Industry and government need to work together to achieve these relationships.

Building such a partnership with Australia is a priority. The two countries have a similar heritage and have had a history of alliance that could ease the building of stronger partnerships in certain areas. Industry generally in both countries is at a comparable stage and biotechnology industries, in particular, have a certain degree of complementarity, rather than competition. New Zealand, for example, has strengths in agricultural genomics, while Australia has experience in its downstream application.

Areas requiring attention to build the relationship with Australia include:

- New Zealand start-up companies need support to bring them on to a level playing field with their Australian counterparts. Working together, New Zealand and Australian industries will constitute a larger force on the world market. But for New Zealand companies to be able to compete fairly with Australian firms, they need to have the same advantages here at home. Government and industry should work together to examine what support New Zealand firms receive compared to similar firms in Australia.
- Taxation and regulation between the two countries should be harmonised. The support that start-up firms receive is one side of a coin. The other is the barriers that firms face in setting up.

We recommend that New Zealand and Australian industry compare the environment in which start-up biotechnology firms operate in the two countries. Government may need to act later to improve New Zealand's environment.

CASE STUDY | Queensland biotech business mission – An Australian partnership

Queensland's proactive approach towards biotech partnerships with other countries has spurred its growth.

Australia is a major biotechnology player with 120 core biotech companies with an annual turnover of nearly A$1 billion.

Queensland is particularly strong in marine therapeutics, biomedical research, extraction and manufacturing of high value pharmaceuticals and tropical and temperate fruit genomics – areas in which New Zealand has complementary capabilities.

In March 2003, a successful biotech business mission from New Zealand, including seven biotech companies, visited Queensland to examine partnership opportunities.

Moves are also under way to establish a 'not-for-profit' foundation in the United States to facilitate the collaboration of life sciences research between the US and New Zealand. The aim is to ensure that New Zealand research remains internationally competitive and can access international grant money from various government and philanthropic sources such as the National Institute of Health and the Gates Foundation.

We should consider the benefits to New Zealand in positioning ourselves as the key international arena for intellectual debate and focus on the coordination and development of international biotechnology protocols. We are well placed to do this given our neutral position between the economic powers of US, Europe and Asia, and could use such a role as a platform to showcase our strength and foresight in the development and application of biotechnology within a rigorous international environment. This should also include a review of our current standing in relevant international scientific bodies such as the NATO Foundation and the Human Frontiers For Science Programme.

The United States is an important partner for the commercial development of biotechnology. Good relations exist at scientist-to-scientist level. The key is to build stronger commercial relationships and open up new market opportunities.

One way this can be achieved is through the establishment of offshore marketing bases amongst customers to provide a platform for New Zealand biotechnology companies to promote market-led capabilities, establish appropriate partnerships, stimulate investment and facilitate the entry by biotechnology companies into the US market.

	Recommended Actions	Responsibility	Timeframe
Action 24	That the Government and industry actively promote New Zealand biotechnology abroad through effective branding, presence at international fora and hosting international conferences in New Zealand.	Government (Industry New Zealand) Industry	Long-term action
Action 25	That industry and Government set in place a programme of initiatives to stimulate the formation of international biotechnology partnerships. This may include: ■ Implementing an offshore marketing base (or bases) in regions with strong biotechnology markets; ■ Reinforcing links with counterpart Australian industry bodies to identify common barriers to the establishment of biotechnology start-up companies; and ■ Developing a programme working at individual company level to help identify overseas business partners (not limited to biotechnology) that can 'add value' on the route to market.	Government (Industry New Zealand, Ministry of Economic Development, Ministry of Research, Science and Technology) Industry	Long-term action
Action 26	Create a not-for-profit organisation, based in the US, to facilitate access to philanthropic and government funds from such groups as the National Institutes of Health and the Gates Foundation.	Government (Industry New Zealand)	Immediate action
Action 27	That Government and industry investigate the status and benefits of strategic alliances with global bodies including, for example: ■ NATO Foundation; and ■ Human Frontiers for Science Programme.	Industry Government (Industry New Zealand)	Immediate action
Action 28	That Government and industry review the benefits of a programme to position New Zealand as the key international arena for intellectual debate and focus on the coordination and development of international biotechnology protocols.	Industry Government (Industry New Zealand)	Long-term action

What New Zealand can offer the world – our life science base strengths

Introduction

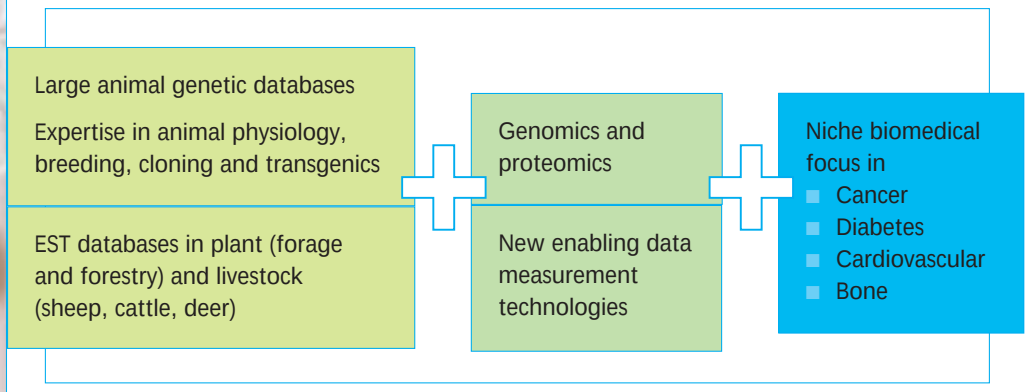
With a large proportion of its government science funding invested in biological sciences over the past two decades, New Zealand has significant science strengths (capability, critical mass, infrastructure and international collaborations) in many areas of the biological and medical sciences relevant to biotechnology. These assets are found across its Crown Research Institutes (CRIs), universities, and private sector companies and research centres. Commercialisation of the research has, over the past three years, seen the development of a set of new science–commercial partnerships and the formation of new commercial biotechnology companies.

The following is not intended to be a comprehensive analysis, nor does it pick out winners. Instead, it surveys where the science capability (skills and resources) lies and where the recent commercial activity is occurring from this science. It profiles eight areas where there are opportunities to build on New Zealand's existing and emerging strengths.

New Zealand's unique blend

New Zealand has significant strengths in large animal biology (in particular being world-leading in overall knowledge of the sheep and dairy cow), as well as having world-class research teams in a number of areas of biomedical science and bioengineering. More recently, New Zealand has also emerged as a world leader in some areas of enabling technology – technology that allows both novel and intensive data collection.

Large animal models combined with animal genomic discovery, enabling technology, and clinical expertise have the potential to accelerate new drug discovery and drug development of relevance to both humans and animals.



New Zealand's comparative advantages

The expertise and assets that can be leveraged for progress in biotechnology are:

- Long-term expertise and applied knowledge in plant and animal breeding, and genetic selection for specific traits;
- Unique germplasm and Express Sequence Tag (EST) libraries in the key species important to New Zealand;
- In depth knowledge of animal and plant physiology and metabolism;

- An understanding of proteins, carbohydrates and fats (especially in dairy) and the ability to manipulate raw materials;
- Established bioprocessing technologies and infrastructure;
- Established bioengineering skills and software design;
- Expertise in international marketing and management of both commodity and consumer food and fibre products;
- World-class biomedical research teams in niche areas of neuroscience, cardiovascular disease, asthma, diabetes, cancer, osteoporosis and bone health;
- A gold standard regulatory regime, and high ethical standards;
- A high animal health status (Category 1, no history of List A (OIE) disease) for biopharmaceutical production from animals;
- The ability to plan and manage clinical trials for international studies; and
- Established R&D/industry clusters in Hamilton (dairy), Rotorua (forestry), Dunedin (biotechnology), Auckland (medical biotechnology), Palmerston North (food technology, plant sciences) and, Lincoln (environmental management and bioprotection/biosecurity).

This strength and depth gives us opportunities in both agri-biotechnology and biomedical areas in the following areas:

1. Large animal-based biotechnologies
2. Plant-based biotechnologies
3. Biomedical science and drug discovery
4. Bioprocessing technologies and biomanufacturing
5. Innovative foods and health.

Other areas where there is the opportunity to build competitive advantage are:

- The unique biological base that New Zealand has in both its marine and terrestrial biodiversity and which provides an opportunity for discovery of unique and valuable biological compounds.
- Environmental management, in which New Zealand has skills and expertise as a result of protecting and enhancing its unique biodiversity.
- New Zealand's capability in niche manufacturing and software design that will be necessary in biotechnology ventures.

Emerging areas for New Zealand's expertise are in developing related agritechnologies and medical technologies and in environmental biotechnology:

6. Agritechnologies
7. Medical technologies and devices
8. Biocontrol, biosecurity and bio-remediation

1. Large Animal-based Biotechnologies

Overview

New Zealand's long history of large animal farming (sheep, dairy, beef, and more recently deer) has led to development of world-class and, in some areas, world-leading science and technologies. This includes knowledge of the ovine, bovine and cervine genomes; reproductive and cloning technologies; large animal models of human diseases; and the use of molecular approaches (including transgenics) to solve animal health issues and enhance human health.

These large animal biotechnologies have the potential to:

- Improve the competitiveness of New Zealand's primary producers through the selection of superior or elite production animals; and
- Create new economic growth through a plethora of biotechnology applications in the biotechnology and agritechnology sectors in, for example, animal vaccines, new gene-based drug therapies, and biopharmaceuticals.

Examples of key science capabilities

- Cloning – the team at Ruakura is regarded as a world leader in cattle cloning, having developed a technique that is four times more efficient than that of other companies. This has led to a partnership with Geron Corporation.
- Reproductive technologies – AgResearch has key capabilities in ovulation control, reproductive physiology, pregnancy establishment, and embryology. World-leading breakthroughs in understanding fertility have come out of access to unique germplasm.
- Transgenics – Linked to cloning and reproductive technologies, New Zealand has developed a capability in transgenesis in cattle and sheep to express high-value proteins in milk for biopharmaceutical purposes. This expertise is coupled with New Zealand's high animal health status (i.e. BSE free), and provides an advantage over other countries.
- Animal genomics – New Zealand has significant expertise in gene discovery and gene functions in sheep and cattle and, to a lesser extent, deer, which can be used to develop products and therapies for animals and humans. Coupled with national herd databases, this is a powerful resource to support gene linkage studies.
- Large animal models – New Zealand has considerable knowledge about sheep. Integration of this knowledge of genomics, reproduction and parasitology provides opportunities for sheep to be models for human health and disease. This could occur in allergy control, foetal growth and prematurity, and heart failure. Large animals provide unique in vivo longitudinal sampling and challenge experiments.

Examples of commercial activity/new enterprises

- Ovita consortium – This new partnership between the sheep (meat and wool) industries and AgResearch aims to build and exploit knowledge of the sheep genome and its associated IP for both pastoral industry gain and for human health targets through a subsidiary, Covita.
- PPL Therapeutics – AgResearch has developed commercial and scientific links with the world leader in transgenic animal technology, securing the freedom to operate for future New Zealand biotechnology enterprises in the biopharmaceutical arena.
- ViaLactia Biosciences and Livestock Improvement Corporation have recently formed the BoviQuest consortium, which will use a combination of the advances in bovine genomics and over 60 years of herd-testing records to identify unique genotypes. Products will be both genetic tests and opportunities to enhance the production and composition of milk.

2. Plant-based Biotechnologies

Overview

New Zealand has extensive knowledge of the biology of industrially significant plants – grasses and other pastoral plants, trees and crops (both arable and horticultural). This includes access to unique germplasm and rapidly growing genome databases, and offers this country the chance to use plant biotechnologies (including transgenesis) in the following ways:

- To dramatically improve the efficiency of our primary producers;
- To generate new agri-biotechnology enterprises based on applications that modify plant growth, health and physiology;
- To use plants in bio-remediation; and
- To create transgenic plants for use in producing biopharmaceuticals.

Examples of key science capabilities

- Merinet – a new cross-organisational initiative set up to create critical mass in plant biotechnology. It brings together the leading edge NERF researchers from CRIs and universities in New Zealand. It is focused on basic research to identify and protect genes involved in plant flowering and branching.
- Palmerston North science cluster – this collaboration has formed from a long historic base in plant science. It involves AgResearch, Crop and Food, Massey University and HortResearch and will develop skills and resources in key plant technology platforms.
- Forest Research – is transforming its research capability toward biomaterials from plants (including bioplastics and biopolymers) through manipulation and modification of plant cell wall development.
- Genesis – New Zealand's largest biotechnology company has large EST databases in the areas of forestry, forage grass and fruit trees. It has built a high throughput capability in functional genomics. It is also focusing on developing valuable IP from screening these databases for novel molecules.

Examples of commercial activity/new enterprises

- Genesis – has been active in the plant biotechnology area for a number of years. Its focus is the identification and commercialisation of plant signalling genes which control growth, development, crop yield and quality, and stress response. Genesis has developed a portfolio of IP including patents on the lignin pathway, and is involved with international consortia in the forestry area (Arborgen).
- The seed industries (Agricom NZ and Wrightson) and livestock industries are involved with AgResearch and Crop and Food Research, among others, in developing ryegrass and arable cultivars with enhanced energy sources to produce step changes (+10%) in animal productivity.
- Pastoral Genomics Consortium – this partnership of the dairy, meat, wool and game industries, with AgResearch, is developing a platform in white clover genomics.

3. Biomedical Science and Drug Discovery

Overview

Whilst a small country on a global scale, New Zealand has some outstanding individuals and teams contributing to advances in biomedical knowledge and the development of medical technologies. Two excellent medical schools at Auckland and Otago universities (with branches in Christchurch and Wellington) have established a tradition and numerous examples of internationally competitive medical research. This has developed a noteworthy capability that can be used in drug discovery and development. There are almost unlimited opportunities to create wealth through improving human health and knowledge.

New Zealand has strengths in:

- Neuroscience
- Cardiovascular disease
- Asthma
- Diabetes
- Cancer
- Osteoporosis and bone health.

Examples of key science capabilities

- The Centre for Molecular Biodiscovery comprises a cluster of five leading research groups at the University of Auckland. The focus will be on the use of new technology for genomic discovery and the innovative development of new medicines for infectious diseases, diabetes and cancer.
- The National Centre for Growth and Development is a centre of excellence aiming to understand the biology of early periods of life and its consequences for health and disease in adult life. It involves Auckland, Otago and Massey universities.

- The Malaghan Institute of Medical Research has expertise in understanding immunological mechanisms of disease, and developing therapeutics, specifically in the areas of tuberculosis and asthma. They have recently issued a patent for an asthma vaccine.
- Industrial Research Ltd (IRL), Massey University and the universities of Otago, Canterbury and Auckland have medicinal chemistry expertise undertaking studies of small molecule drug candidates by chemical synthesis.
- Glycosyn, a new process development, scale-up manufacture facility for clinical trial material is now open at IRL.

Examples of commercial activity/new enterprises

There are many examples in this area. What follows is a snapshot of recent activity:

- Protemix, a recent start-up, aims to develop new therapeutics for Type 2 diabetes mellitus.
- Viryonix is developing an HIV drug based on goat plasma. This has finished Phase 1 trials.
- Genesis has a psoriasis vaccine PVAC undergoing Phase 2 clinical trials.
- BLIS Technologies has successfully developed and marketed a throat guard product, which confers protection against streptococcal throat infections. This was developed from basic research on bacteriocin-like inhibitory substances at the University of Otago.
- Antipodean Biotech is undertaking pre-clinical development and human studies in New Zealand with mitoquinone, a chemical compound for treating Huntington's disease and Freidrich's ataxia.
- ProActa Therapeutics Limited is developing cytotoxic prodrugs for the treatment of cancer. These prodrugs are activated under hypoxic conditions, making them effective at targeting solid tumours where other anti-cancer treatments are not successful.

4. Bioprocessing Technologies and Biomanufacturing

Overview

New Zealand companies have been handling and processing biological material for over a century. We know how to extract fine chemicals from meat and fish wastes, to retain the biological activity of sensitive components such as enzymes. As the potential of minor components of plants, microbes and animals are identified, this country is well placed to develop the bioprocessing technologies necessary to develop, manufacture and market these high-value molecules for the world.

New Zealand has a Category 1 animal disease free status, providing it with a significant competitive advantage as a source of animal bioactives and biochemicals.

Examples of key science capabilities

- IRL's bioprocessing teams cover the spectrum in bioprocessing: inoculation, fermentation, separation technologies, including supercritical extraction technology, etc. They are Good Manufacturing Practice (GMP) certified.

Examples of commercial activity/new enterprises

- NZ Pharmaceuticals – this long-established company started off extracting biochemicals from the meat industry and in recent years has focused on biochemicals and extracts from plant materials.

New Zealand has a number of companies that can contract manufacturing and formulate products. One example is:

- IRL Biopharm – this is a contract manufacturing business focused on developing and manufacturing novel secondary metabolites. The company has focused over the past two years on developing and manufacturing toxic molecules for attachment to tumour-specific monoclonal antibodies now being developed in the clinic for various cancer indications.

5. Innovative Foods and Health

Overview

New Zealand is, above all, a food exporter, being the biggest dairy trading nation. We are well placed to exploit emerging demographic and consumer trends that see foods as a route to improved health and well-being. New Zealand foods offer a diverse biological resource of food ingredients or components that can satisfy the growing international demand for nutriceutical, bioactives and functional health foods. The convergence of nutritional science, biomedical science, and food technology is an emerging area of biotechnology that we are well placed to exploit. We can add real value to our considerable export receipts from foods.

Examples of key science capabilities

- Fonterra Research Centre – This centre has specific expertise related to understanding the raw constituents of milk, its structure and functionality. They are world-leading in the genetics and metabolism of dairy lactic acid bacteria, utilising fermentation and enzyme science to develop novel flavours technologies for industrial application.
- Universities – Massey, Otago, and Auckland have key capabilities in food technology, product and process development. Massey has the Institute of Food, Nutrition and Human Health, while Auckland has key strengths in nutrition through links with its medical school.
- CRIs – AgResearch, Crop and Food and HortResearch each have significant capability in added-value food products and bioactives. This capability covers dairy-, meat-, fruit-, vegetable-, and arable-based products.
- A new as yet small initiative at HortResearch is looking at optimising muscle gain and maintenance in both healthy and sick individuals through the use of certain natural derived nutritional supplements. The programme is also working with elite athletes to maintain and gain muscle during training.

Examples of commercial activity/new enterprises

- The Fonterra Group is our largest food company. Two areas where it is seeking high value opportunities are:

  Lactopharma – A recent consortium partnership between Fonterra and the University of Auckland focusing on biomedical compounds with unique activity from milk and colostrum for the development of functional food products, specialty ingredients, nutriceuticals, and pharmaceuticals.

  New Zealand Milk – This carries New Zealand's key dairy-related consumer brands and has significant expertise in marketing and selling functional food products internationally. Probiotics have been clinically proven to enhance the immune response and decrease harmful bacteria in the gut.

- GraceLinc is a joint venture between Crop and Food Research and Industrial Research which has been formed to commercialise Glucagel, a soluble fibre gel and nutriceutical ingredient based on barley.

6. Agritechnologies

Overview

New Zealand is well known for its low cost, efficient pasture-based production system, which has led to the development of world-leading technologies in areas such as electric fencing, milk meters and animal health products. A growing convergence between biological and physical technologies spawns biotechnology-based opportunities in agritechnology that will either be opportunities in their own right or will support other areas of biotechnology. There are three areas where this will be specially so:

- Diagnostic sensors are becoming key tools for measurement or validation systems. Many of these are based on biochemical reactions.
- Animal health products (including vaccines and diagnostics).
- Computer based decision support systems for production systems.

Examples of key science capabilities

- Expertise in high-tech sensor technologies in a number of institutions, including AgResearch (Sniffertech) and IRL.
- Development of solid-state reproductive and milk-residue sensors at HortResearch and Sensortec.
- The Dexcel-led team that is combining sensors and fractionation technologies in milking machines that can detect and separate the biologically valuable proteins and peptides from the whole milk.
- Expertise in computer-based modelling of farm operations and systems for animal, horticultural and arable farming operations.

Examples of commercial activity/new enterprises

- ICPBio – This was one of New Zealand's first biotechnology companies. Its focus is animal health products (in particular reproductive pharmaceuticals, embryo handling and storage media, pregnancy determination products and animal disease diagnostics).

7. Medical Technologies and Devices

Overview

Medical technologies cover medical electronics, instrumentation, software and information technology, non-invasive sensory technology and dental technology. These were identified as a significant opportunity for New Zealand during Foresight (1999) because these markets are large and growing in developed economies. This growth is likely to continue because of demographics, ageing populations and rising incomes in first- world countries. The medical devices field occurs at the meeting of science, technology and engineering. It allows us to leverage off our strengths in biological and medical sciences as well as niche-oriented manufacturing and information technology and specialised electronics.

Examples of key science capabilities

- Auckland University's Bioengineering Research Group has been working on the biomechanical functioning of the heart for 23 years. The research aims to identify the mechanisms of the heart and create computer models for events such as heart failure. They have developed computational bioengineering software (the Computer Image Modeller) that allows clinicians to see three-dimensional images of the patient's heart from two dimensional magnetic resonance images.
- HortResearch's Bioengineering Technologies research group is studying stress, disease and human performance data that it is hoped will lead to diagnostic instrumentation and novel therapies for diagnosis and treatment of disease. The work includes new ways of respiratory and anaesthetic control and better, faster, non-invasive diagnosis equipment.

Examples of commercial activity/new enterprises

- Fisher and Paykel Healthcare's success in human respirators was based on DSIR science.
- NeuronZ and the Liggins Institute have developed baby monitors from their basic research on paediatric disorder. These are being commercialised through TruTest.
- MoleMap NZ has produced a melanoma imaging system for diagnosing melanomas.

8. Biocontrol, Biosecurity and Bio-remediation

Overview

New Zealand has a temperate climate and fertile soils, leading to a productive, but vulnerable economy driven by primary industry. We know a great deal about how to grow plants and trees and how to farm livestock and harvest fish from the sea. While our focus and dependency on these industries makes us vulnerable, it also offers opportunities. Biotechnology has the potential – and in many cases has already begun – to provide solutions to existing and potential biosecurity threats though a range of biocontrol and detection technologies. Biotechnology can also help reduce, through bio-remediation technologies, the environmental damage caused by past use of chemicals and other hazards. We have a strong research base in environmental research and sustainable production that can and is being leveraged into environmental technologies and new enterprises.

Examples of key science capabilities

- The new centre for Advanced Bio-protection Technologies based at Lincoln University, with AgResearch, Crop and Food Research and Massey University, is addressing plant protection and new biosecurity technologies. The centre will develop sensor technologies, molecular identification systems and mathematical models to protect against pest and disease incursions.

Examples of commercial activity/new enterprises

- The company Biodiscovery is undertaking high through-put screening of microbes for their ability to destroy plant pests and crop diseases. The firm is looking for novel bioactives, in particular peptides and proteins for use in organic pesticides.

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GROWING THE BIOTECHNOLOGY SECTOR IN NEW ZEALAND | A FRAMEWORK FOR ACTION

REPORT FROM	THE BIOTECHNOLOGY TASKFORCE
MAY 2003	ISBN 0-478-25403-2