NEW ZEALAND'S RESEARCH, SCIENCE & TECHNOLOGY PRIORITIES FEEDBACK DOCUMENT

SUBMISSION BY
NZ BIOTECHNOLOGY 2003 INC (NZBIO)

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1. BACKGROUND

NZBIO is New Zealand's national industry association representing bio-based industries and organisations. With approximately 300 members, NZBIO actively represents the interests of the scientists, entrepreneurs, investors, companies and service providers that are active in driving and supporting New Zealand's rapidly growing bioeconomy.

More than 70% of New Zealand's export earnings are derived from biology-based industries spanning human and animal health, agriculture, horticulture and other natural products. Exports include finished products and ingredients destined for the food, cosmetics, nutraceutical and pharmaceutical industries.

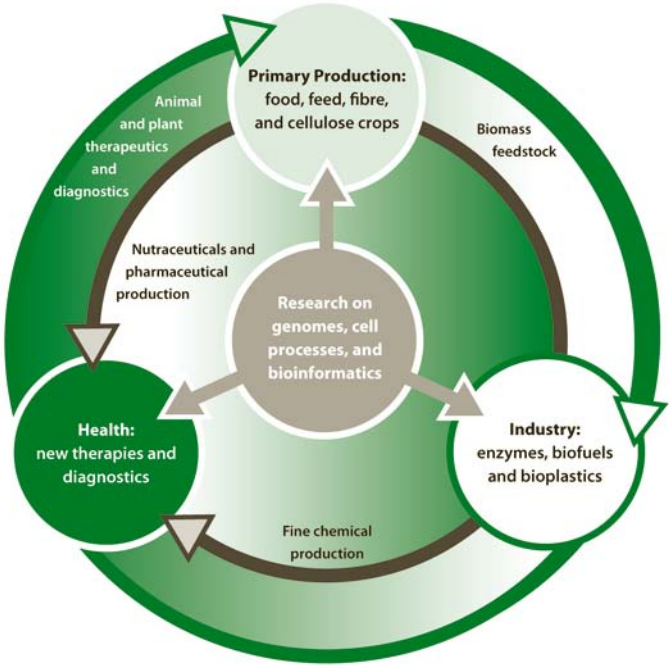
NZBIO is strongly aligned to the OECD's concept of an integrated bioeconomy[1] that includes bio-based applications in Primary Production, Health & Industry. NZBIO supports organisations engaged in all three application areas.

Examples of what is included in each application area by the OECD are outlined below.

Primary Production:

All living natural resources such as forests, plant crops, livestock animals, insects, fish & other marine resources. Illustrative examples include but are not limited to:

- Plants (New crop varieties -For food and feed, Feedstock for industrial applications, Forestry, Plant diagnostics)
- Animals (Animal breeding, animal diagnostics & therapeutics, applications to marine resources and others.)



[1] OECD International Futures Programme The Bioeconomy to 2030: Designing a Policy Agenda (2000)

Health:
Human health related applications such as pharmaceuticals, nutraceuticals, diagnostics, medical devices. Illustrative examples include but are not limited to:

- Therapeutics. (Biopharmaceuticals, experimental treatments, small molecule therapeutics and others, including generics.)
- Diagnostics.
- Pharmacogenetics.
- Functional foods & nutraceuticals.
- Biopharmaceutical Manufacturing
- Medical Devices.

Industry:
Chemicals, plastics, enzymes, mining, pulp and paper, biofuels and environmental applications. Illustrative examples include but are not limited to:

- Production of chemicals
- Production of biomaterials
- Fermentation
- Niche manufacture
- Industrial enzymes (for food, feed & beverages, detergents, textiles, pulp & paper and others)
- Environmental (Bioremediation, Bio sensors and others)
- Biotechnology in resource extraction
- Biorefineries
- Biofuels

In addition, NZBIO also represents members who are "enablers" of the bioeconomy

- Technology Transfer Offices
- Commercialisation & business development consultants
- Venture Capital & Private Equity firms
- Institutional and Private Investors
- International Partners
- Service Providers... and others.

These organisations and individuals are an essential component of a highly productive, internationally successful, and export generating ecosystem of innovation and commercialisation based on New Zealand's excellence in the application of biotechnology to solve current and future challenges facing the globe.

2. OVERVIEW & GENERAL COMMENTS

NZBIO is extremely supportive of the proactive stance the Government has taken in placing a significant emphasis on innovation as a driver for improved economic performance, within the broader framework of its six key policy drivers. NZBIO has reviewed the document "New Zealand's Research, Science & Technology Priorities: Feedback Document" with the understanding that changes made in the other five areas, namely Regulatory Reform; Skills & Education; Infrastructure; Taxation; and Public Sector Services, will all significantly influence the effectiveness of the proposed RS&T system & the impact of New Zealand's Innovation sector.

NZBIO specifically would like to commend the Government for its focus on:

- Placing a strong emphasis on science & innovation as economic drivers;
- Removing excessive regulation;
- More effective business assistance to encourage R&D, commercialisation & international export performance;
- Review of the CRI Model; and
- Assessing methods for increasing business investment in R&D.

The Strategic Direction of the New Zealand Science System

NZBIO supports the view of the Government that the key challenge for New Zealand is to increase its productivity and relative wealth, without sacrificing its unique environment. The general principles outlined in the feedback document are a clearly enunciated suite of principles on which the new system has been developed.

However, NZBIO would like to encourage caution with respect to a "sectoral approach" (General Principle # 3) that does not encompass enabling technologies such as biotechnology, nanotechnology, ICT and the like. These often underpin innovation and novel products and services in a range of sectors.

Additionally with respect to the principles underlying priority setting, for the purposes of this document, NZBIO assumes that internationally recognised expertise and competitive advantage in niche areas including health and industrial biotechnology have been considered in the "advantage already defined sectorally (p6).", in addition to the well known competitive advantages in the primary sector.

NZBIO is also pleased to see a focus on effective international linkages and collaborations with an emphasis on these where there is an advantage to New Zealand. NZBIO believes a balance between building domestic capability and linking that capability internationally will deliver rewards for New Zealand in the short, medium and long term.

NZBIO applauds the three operational principles outlined and believe they signify a positive step forward if applied consistently through the development, implementation and execution of the proposed new structure.

3. VOTE RS&T: THE NEW INVESTMENT STRUCTURE

Overall the new Vote RS&T Investment structure is clear, easily understood and appears to address the needs of the New Zealand RS&T system.

NZBIO would like to raise the following issues in the proposed investment structure and will develop these further in the following sections:

- Whilst the structure diagram refers to the "Biological Economy", the text appears to only incorporate the primary production and food sectors within this. The OECD is clear in its portrayal of a bioeconomy that applications to Health, Industry and Primary Production are components of a bioeconomy. NZBIO would like to see the ability for biotechnology-based organisations to be categorised under High-Tech Industries (biodevices, digital technologies and software, biomanufacturing etc), Energy (biofuels) and Hazards (biosecurity).

- NZBIO is concerned that Health and the Environment appears only in the 'Public Good Outcomes" sector. New Zealand has vibrant human therapeutics, diagnostics and medical technologies industries, in addition to emerging products and services based on R&D in the environmental sector. To classify these areas under "Public Good Outcomes", rather than include them also in "Economic Outcomes", appears to detract from their very real track record & capability for novel product development and enterprise & wealth creation. All of these industries are currently contributing to New Zealand's existing high growth bioeconomy and to limit their potential impact by focusing only on their 'Public Good Outcomes" benefits will limit New Zealand's ability to extract maximum value & economic gain from its RS&T system.

NZBIO supports the additional work being done with respect to the development of other programmes to assist in development and commercialisation under the Government's broader Economic Growth Agenda and is confident that these programmes will work synergistically with the Vote RS&T Investment structure proposed. NZBIO also notes and is highly supportive of the inclusion of "scope for the identification and support of emergent areas of innovative research" and would be very keen to see more detail as to how this will be encouraged and supported.

4. FEEDBACK VOTE RS&T INVESTMENT STRUCTURE

VOTE RS&T OVERALL INVESTMENT STRUCTURE

NZBIO supports the overall investment structure. We make recommendations on the weighting of funds and subsectors that need to be considered within the broader sector descriptors, and for investment for translational research and commercialisation below.

PRIORITY INVESTMENT AREAS

NZBIO supports the three broad investment areas: Economic Outcomes, Public Good Outcomes, Capabilities and Infrastructure. In particular, within the Economic Outcomes investment structure, we applaud the focus on where NZ can demonstrate or develop international competitive advantage.

BIOLOGICAL ECONOMY SECTOR STRUCTURE

NZBIO commends the Government on recognising the Biological Economy. The importance of the Primary Production and Food, including functional food and nutraceuticals, sectors are well recognised in the document. However, the Biological Economy definition used (p10) appears too narrow and is not consistent with the international view on the broader bioeconomy. NZBIO is concerned that the other key areas of the bioeconomy important to New Zealand are not considered. Health, Industrial products and Environmental applications need to be recognised as part of the Biological Economy and of key importance to New Zealand's future economy.

The "Biological products and processes" sector of the Biological Economy sector description also needs further clarification. If cross-matching to the areas of potential platforms (p14) is an indication, it would appear that "Biological products and processes" is limited to "Higher value wood products".

NZBIO assumes that a broader view of the Biological Economy was intended and, therefore, the scope of the Biological Economy investment area should be expanded. NZBIO would be very concerned if the application of biotechnology to create and develop new domestic and export products for health or industry were not considered in-scope for the biological economy.

NZBIO recommends that the Biological Economy description be reworded to specifically include the following areas:

- **biological products and processes for industrial applications**
- **products for health, including human therapeutics and diagnostics, animal health products, medical devices, digital technologies and software**
- **bio-based energy and environmental products and services**

New Zealand can be successful in focused areas of Health:
The following discussion demonstrates that New Zealand has a growing and economically important human therapeutics industry. NZBIO does not suggest that the human health sector of the Bioeconomy is *more* economically important than other sectors of the Bioeconomy. However, this area has developed rapidly in the last few years and is poised for significant growth in the short, medium and long term. Therefore NZBIO suggests that human therapeutics is important enough to be considered for investment within the Biological Economy investment area or a dedicated investment stream.

In the RS&T priority document, the health industry, beyond nutraceuticals, does not seem to have any recognition under Economic Outcomes. Innovation in human therapeutics, diagnostics or medical technology does not fit well under the descriptors for "Biological Economy" and instead appear to be considered only under 'the "Public Good Outcomes" benefit. While medical devices and devices for biological research, digital technologies and software might fall under "High Technology Industry" NZBIO stresses that companies engaged in these activities are considered by the OECD, and by the individual companies themselves, to be part of an integrated bioeconomy. These companies deliver significant economic benefit through new products and services in their own right.

Prospects for New Zealand's health biotechnology sector:
Major changes are happening to the structure of the global health and pharmaceutical industry that provides opportunity for small players in human therapeutics to be competitive and achieve significant economic returns to New Zealand. In fact, a number of health biotechnology firms are already contributing significantly to foreign direct investment, R&D expenditure, export revenues and economic growth. New Zealand has sound firms that are already strong exporters of manufactured health products, largely for generic drugs, but with an increasing focus on proprietary products arising from research activities. For example, three firms, Douglas Pharmaceuticals, New Zealand Pharmaceuticals, and AFT Pharmaceuticals have exports worth up to $200 million per annum.

Opportunities for the New Zealand human therapeutics industry have been analysed in depth by NZBIO and are due to be published at the end of November 2009. NZBIO urges the Government to fully consider the content of NZBIO's report when it becomes available in November. Some key examples are given below:

> **New Zealand Pharmaceuticals Limited** (NZP), established in 1971, supplies the global pharmaceutical industry with pure biochemicals. NZP also manufactures a range of biochemicals and natural extracts for the international health food, cosmetic, biotechnology and aquaculture industries. NZP has a dedicated Research & Development team and FDA approved manufacturing facilities. NZP has a strong export focus with over 95% of its products being exported to all parts of the world and is ranked in the New Zealand top 500 list of companies.
>
> **Douglas Pharmaceuticals**, founded in 1967, is one of the fastest growing pharmaceutical companies in Australasia. They export a range of ethical generic medicines to Europe and Asia, with plans to expand in the USA. Douglas employs around 450 staff in laboratories and manufacturing sites in Auckland.
>
> **AFT Pharmaceuticals** is 100% NZ privately owned and NZ based pharmaceutical company established in August 1998 in New Zealand. AFT adapts existing products to new applications and targets niche applications not addressed or recognized by the multinational big pharmaceutical companies. This requires developing the product through clinical trials to full approval. AFT also owns a significant portfolio of IP (trademarks, patents) and licenses. AFT has now expanded to Australia, Malaysia and South East Asia. It is currently the second biggest NZ owned pharmaceutical company with

projected sales for the year ending March 2010 to be over $37 million, over 40% of which will be export sales.

At an earlier stage in their development, companies like these often look to government sources of research funding to develop potential new products.

New Zealand also has examples of companies at an earlier stage of development. Some of these might well grow beyond the size of NZP or Douglas Pharmaceuticals but they require access government sources of research and commercialisation funding to expand their product or service base. A few illustrative examples of the range of New Zealand companies successfully engaged in human or animal health are given below:

South Pacific Sera produces animal blood, serum and protein products for use in therapeutic, cell culture, microbiology and immunology applications around the world. Privately owned, the company has operated in the biologicals field since 1988.

Pacific Edge Biotechnology Limited (PEB) is a New Zealand biomedical company, formed in 2001 and listed on the New Zealand stock exchange in 2002. Pacific Edge develops and commercialises diagnostics and prognostics for cancer. Four product prototypes are now in late stage development with two of these in clinical trial phase and close to being market ready. An early diagnostic and monitoring test for bladder cancer, *Cxbladder™*, will be Pacific Edge's first product. Negotiations are currently underway with several parties interesting in commercialising this test for use by urologists and it is due for release to the international market early in 2010.

Argenta, founded in August 2006, is the world's first Contract Development and Manufacturing Organisation dedicated to animal health. Argenta exports to over 40 countries and employs over 100 staff.

Comvita, established in the 1970s, is a successful exporter well known for their natural health care products. Comvita listed on the New Zealand stock exchange in October 2006. Comvita is actively engaged in research on therapeutic effects to expand their product range.

Seperex, Nutritionals Limited is a private biotechnology company founded in 2004. They discover, manufacture and market bioactive substances for human health, both domestically and for export.

CoDa Therapeutics is a biopharmaceutical company developing wound healing and other therapies. Wound healing is a multibillion dollar business. CoDa's platform product, Nexagon® has passed Phase 1 clinical trials and CoDa were successful in attracting US$26 million venture capital funding, a significant direct contribution to the New Zealand economy.

It appears that the kind of research that supported the development of the emerging and increasingly successful human therapeutics and diagnostics sector would no longer be actively supported under the new investment structure.

NZBIO believes that the New Zealand Health sector of the Bioeconomy is poised for dramatic growth and must be recognised and supported in the investment structure as a key component of an integrated bioeconomy.

New Zealand is also active in Industrial Bio-industry.
Industrial and environmental biotechnology is considered by the OECD to be the third wave of biotechnology[1], the first being Health and the Second being Primary Production. Therefore, activity in Industrial and Environmental applications within the Bioeconomy is smaller but will grow to become as globally significant as Primary Production. Therefore, NZBIO believes that Industrial and Environmental applications should be considered in-scope for the Biological Economy or Energy and Minerals investment areas.

It is not clear whether research leading to bio-based Industrial and Environmental businesses would sit within the investment structure.

A few illustrative examples of New Zealand companies engaged in Industrial and Energy Biotechnology include the following:

> **Aquaflow Bionomic Corporation**, founded in October 2005, is developing 'environment friendly' and economically attractive biofuel from wild algae harvested from open-air environments. They are developing IP and production processes in three areas: harvesting of wild microalgae, conversion of algae into biocrude and derived products, upgrading water quality. Boeing is looking at a number of possible non fossil sources for jet-fuel and it has been working with Aquaflow in this regard.
>
> **Ecodiesel Limited** is a manufacturer of biodiesel in New Zealand. They produce a high quality, sustainable biodiesel from tallow, a by-product of the New Zealand meat processing industry. In March 2009, they achieved a New Zealand first when their biodiesel was blended by major oil companies for sale at the pump to New Zealand retail consumers. When their purpose-built facility opens in 2010, they will be New Zealand's largest commercial-scale, biodiesel manufacturing operation. They will initially produce 20 million litres of biodiesel annually increasing to 40 million litres annually by 2012.

CURRENT WEIGHTING OF FUNDS AND WHERE EMPHASIS SHOULD BE PLACED

NZBIO recommends that the funding for the Biological Economy sector be increased to recognise a broader scope and higher economic potential.

Of the $305 million investment in the Economic Outcomes sector, the Biological Economy receives $165 million. NZBIO supports this high relative weighting given to the Biological Economy and believes there is justification for a further increase. The OECD predicts that for New Zealand, the potential contribution of the Bioeconomy to GDP will be up to $18 billion by 2030[1]. If the OECD is correct in its assumptions, then major growth of New Zealand's economy will be through the Bioeconomy and government investment should be attributed accordingly.

Also, the inclusion of the emerging human therapeutics and diagnostics sector of New Zealand into this category would support additional funds being allocated to this area.

NZBIO recommends that within each investment outcome area there are specific funds created and ear-marked for translational research and commercialisation. These funds should be significantly increased from current levels.

NZBIO suggests that the share of commercialisation and business support funds (eg. PSAF and TechNZ) into the Biological Economy should be increased and the scope of the Biological Economy broadened.

Simplification within each investment area through vertical integration of funding is a good thing. However, NZBIO is concerned that there does not appear to be a transparent mechanism to ensure appropriate balance between early research investment, later stage translational activity, and investment for commercialisation. Where do emerging companies go for support if instruments like the Pre-seed Accelerator Fund (PSAF) and TechNZ are not held separate and visible? In many countries private investment supports later stage development and early commercialisation.

However, New Zealand lacks an effective venture capital and private equity market, and co-funding from New Zealand companies is poor. Government has been responsive to this need through providing funds such as the PSAF, TechNZ, and others. Groups and organisations engaged in early commercialisation activities need the assurance of visible public funds 'ring-fenced' for commercial activities and a viable venture capital, private and public equity industry. Greater certainty of funding from public sources helps attract co-investment from private sources and improves economic outcomes.

Currently the PSAF spend is 30% into Biological Economy and 70% into High Technology Industries. The TechNZ spend is 7.5% into Biological economy and 92.5% into High Technology Industries. The single greatest impediment to commercial success of NZBIO's member companies is access to capital for bio-company establishment and growth. Given the importance of driving research within the Biological Economy through to economic outcomes, the share of commercialisation and business support funds, such as PSAF and TechNZ, into the Biological Economy should be increased.

5. FEEDBACK: STRATEGIC RESEARCH PLATFORMS

NZBIO supports the investment in Strategic Science Capability as a good step forward. NZBIO believes that the underlying criteria for potential strategic research platforms could be further improved with the recognition of biotechnology as a "*Disruptive*" technology. We agree that as an enabler of the broad breadth of the Bioeconomy, as defined by the OECD, biotechnology is indeed a pervasive technology. However, biotechnology is also expected to give rise to the greatest number of new *Disruptive* technologies that fundamentally re-shape the way we do business. It is important that the concept of Disruptive technologies is recognised in the strategic research platforms.

NZBIO recommends that biotechnology be added to the "underlying criteria for potential strategic research platforms" as follows:

The underlying criteria for potential strategic research platforms are:

- demonstrated strategic relevance to government and/or sector goals
- research that is significant in scope, size and duration, and
- developing at least one of these key areas:
  - **disruptive technologies, including biotechnology**

The OECD expects that the major benefits of biotechnology within the Bioeconomy will be, in ranked order of gross value added, through Industry (39%), Primary Production (36%); and Health (25%).

NZBIO recommends that the ranking of potential platforms reflect the relative weighting of economic benefit predicted by the OECD.

NZBIO recommends that the following additional priority areas be added to the Biological Economy Sector as discussed in previous sections:

- **Maximise economic return from New Zealand's capability in health, including diagnostics, medical devices, digital technologies & software, biologics and others**
- **Transform New Zealand's biological economy through Industrial bio-based technology**
- **Transform New Zealand's biological economy through disruptive science and technology**

NZBIO recommends that the following additional platforms be added to the Energy and Minerals Sector:

- **Increase New Zealand's wealth by exploiting Bio-based energy**

6. FEEDBACK: DEVELOPING PEOPLE & INFRASTRUCTURE

NZBIO is pleased to see that the Government recognises that talent and international relationships are key areas for investment. NZBIO considers that these two areas are of top priority and should be given strong emphasis.

TOP TALENT

NZBIO recommends that the Top Talent fund be expanded to support excellence in commercial skills and entrepreneurship, not just excellence in science. The fund should attract talent from overseas as well as from within New Zealand.

Attracting and retaining top talent was the second highest priority impediment to commercial success of NZBIOs member companies. The talent 'gap' is both in science capability and commercial capability. The Government Top Talent priority area addresses science talent but not commercial talent. NZBIO believes Government investment is required to attract, retain, and develop top commercial and entrepreneurial talent.

INTERNATIONAL RELATIONSHIPS

NZBIO recommends a larger International Relationships fund with expanded scope to go beyond research collaborations to researcher -investor and researcher-business collaborations.

RS&T is becoming increasingly global and so is the commercialisation of RS&T. New Zealand needs to actively seek external talent, research partners, commercial partners and investors in order to maximise the commercial returns from limited resources and overcome the disadvantage of geographic dislocation from markets. The international partnerships fund should be increased and broadened.

7. SUMMARY OF RECOMMENDATIONS & FEEDBACK

The purpose of the recommendations made by NZBIO is to improve the environment for achieving commercial outcomes from New Zealand's bio-based sector. Recommendations fall into five areas:

1. To broaden the scope of the Biological Economy to encompass additional subsectors of the bioeconomy that have high economic potential.
2. To strengthen government funding for commercialisation
3. To support the development of biotechnologies that will be disruptive to the economy
4. To support commercial talent as well as scientific talent
5. To support international commercial partnerships with New Zealand's innovation sector

NZBIO RECOMMENDATIONS

1. NZBIO recommends that the Biological Economy description be reworded to specifically include the following areas:
    - biological products and processes for industrial applications
    - products for health, including human therapeutics and diagnostics, animal health products, medical devices, digital technologies and software
    - bio-based energy and environmental products and services
2. NZBIO believes that the New Zealand Health sector of the Bioeconomy is poised for dramatic growth and must be recognised and supported in the investment structure as a key component of an integrated bioeconomy.
3. NZBIO recommends that the funding for the Biological Economy sector be increased to recognise a broader scope and higher economic potential.
4. NZBIO recommends that within each investment outcome area there are specific funds created and ear-marked for translational research and commercialisation. These funds should be significantly increased from current levels.
5. NZBIO suggests that the share of commercialisation and business support funds (eg. PSAF and TechNZ) into the Biological Economy should be increased and the scope of the Biological Economy broadened.
6. NZBIO recommends that biotechnology be added to the "underlying criteria for potential strategic research platforms" as follows:

    The underlying criteria for potential strategic research platforms are:
    - demonstrated strategic relevance to government and/or sector goals
    - research that is significant in scope, size and duration, and
    - developing at least one of these key areas:
        - disruptive technologies, including biotechnology
7. NZBIO recommends that the ranking of potential platforms reflect the relative weighting of economic benefit predicted by the OECD.

8. NZBIO recommends that the following additional priority areas be added to the Biological Economy Sector as discussed in previous sections:
    - Maximise economic return from New Zealand's capability in health, including diagnostics, medical devices, digital technologies & software, biologics and others
    - Transform New Zealand's biological economy through Industrial bio-based technology
    - Transform New Zealand's biological economy through disruptive science and technology
9. NZBIO recommends that the following additional platforms be added to the Energy and Minerals Sector:
    - Increase New Zealand's wealth by exploiting Bio-based energy
10. NZBIO recommends that the Top Talent fund be expanded to support excellence in commercial skills and entrepreneurship, not just excellence in science. The fund should attract talent from overseas as well as from within New Zealand.
11. NZBIO recommends a larger International Relationships fund with expanded scope to go beyond research collaborations to researcher -investor and researcher-business collaborations.