

## **NZBIO Submission in support of ERMA200223**

### **Introducing NZBIO**

NZBIO is a member-based peak industry body representing biotechnology-based organisations. Our members span the development cycle from publicly funded research organisations to commercial entities and come from all sectors of New Zealand's bioeconomy. To be completely clear and upfront regarding any real or perceived conflict, AgResearch is a corporate member of NZBIO along with another almost 100 organisations and 200 individuals.

Our mandate is very much broader than genetic technologies; we represent companies and organisations involved in primary production, such as forestry, farming and food production, industrial and environmental research and technologies, high tech manufacturing, alternative fuels, human therapeutics, diagnostics and devices, animal health products, and so on.

The bioeconomy in New Zealand is a significant contributor to the country's current and future economic wellbeing and is predicted by the OECD to contribute many billions of dollars to the NZ economy by 2030.

To address previous comments about the economics of the sector, a recently released Statistics New Zealand survey indicated that there were a total of 267 organisations involved in bioscience. Pertinent to this proposal, some 15% of these are active in biomedical science and a further 18% are involved in bioprocessing and manufacturing. Of these the 108 core bioscience organisations demonstrated income of \$351m and exports of \$167m.

NZBIO exists to represent its members and to help New Zealand as a whole benefit from our biological resources and biotechnology capabilities, which are internationally recognised. We recognise and act to facilitate the social, environmental and economic benefits of biotechnology and strongly support the bioeconomy's ability to assist New Zealand, and the world as a whole, to meet the global challenges of finite resources, environmental sustainability and increasing demands on healthcare systems.

Because we represent such a broad sector, much of which does not involve any kind of genetic modification, **our view on genetic modification supports coexistence and informed consumer consent.**

Our view is New Zealand is for all New Zealanders and we recognise the role that research, science and technology, including biotechnology, will have to play if New Zealand and the rest of the world are to cope with the challenges ahead. In relation to genetic technologies, this means that, **we support the view of the Royal Commission on Genetic Modification that we must move forward, but with appropriate caution, along the genetic modification path.**

## **Robust regulations are good for the Bioeconomy**

**NZBIO supports a robust regulatory regime.** Strong regulations are good for the bioeconomy. A sound regulatory environment **helps trade** and provides a 'Halo Effect' for New Zealand that says to the world **"New Zealand products are safe and reliable and New Zealand is a safe country to live and do business"**. This applies to all regulations affecting the bioeconomy be it relating to food safety, the regulation of new human therapeutics and medical devices or the application of genetic technologies.

So we are very pleased that, under this application, the proposed work will be done under the close watch of New Zealand's regulatory system and not elsewhere in the world, where regulations in some areas have proven to be insufficient to appropriately manage such research. What will hinder the growth and benefits of a biological economy most is **uncertainty caused by the inability to make a stable decision based on sound information.** Such uncertainty has a negative impact on investment, research and new product development. Regulators need to be empowered to act swiftly and with certainty and apply the regulations according to the relevant legislation and within the context of the benefits to New Zealand and for New Zealanders, as well as the benefit to the peoples of the world.

## **What is the impact of not doing the work?**

NZBIO believes the proposed work is very important, not just for the benefits to NZ through improved standard of living but also for the social benefits it brings here and abroad.

AgResearch's intent is to develop a technology for producing more effective human therapeutics, and producing these more cost-effectively than current technologies allow.

There are major benefits in four areas that we, as a nation, would miss out on if this application is not approved:

- **Control over how these technologies develop**
- **Better and cheaper healthcare for New Zealand and the global community**
- **Jobs and gross added value into the NZ bioeconomy**
- **Ability to close the widening gap with other OECD countries**

I would like to explore each of these in further detail:

**Control over how these technologies develop.** It is safer for the end-users of these types of products, both in New Zealand and the rest of the world to do the work here under our strict and responsible regulatory system

The proposed technology is valuable and addresses large, unmet market needs in healthcare. **Ultimately someone, somewhere in the world will develop this technology or one like it and the end products will be exported globally, and in all likelihood New Zealand will be one of those export markets.**

If this kind of work was conducted in a country where the regulatory system was less robust and where controls are lax or safety less assured than in New Zealand, significant consumer risk may result. The melamine milk powder and contaminated heparin scandals in China should serve as a stark reminder of what can happen in countries where regulations are not respected or enforced.

New Zealand has one of the most robust systems for overseeing, controlling and containing genetic modification work in the world. In our view, it is much better that these technologies are developed **in containment** under the cautious, watchful and socially considerate eye of New Zealand's regulators. We can then be sure that the end products and technologies are safe and reliable, both for use in New Zealand and for use by other countries. If this work were done overseas, where regulators may have their own economic and social interests at heart, rather than those of our small country, we will have less control over the products and technologies that we, as global consumers, will be exposed to.

There is also a commercial benefit to sound regulations. **New Zealand's reputation as a safe and reliable producer is supported by developing this technology under our strict regulatory regime.** Confidence in both the technologies and NZ products overall will grow as a result and New Zealand's international reputation will be enhanced.

**Realistically there is no doubt that these types of technology will exist in the future. So now it is more a choice of whether we, as New Zealanders, want to have some control over the development of these products, that we are likely to consume in the future, or not.**

**Better and cheaper healthcare**, for New Zealand, and the global population and especially for the poorer nations of the world

Affordable healthcare is recognised by the OECD as one of the major challenges facing the globe. A 2008 study by the World Health Organisation reported that globally each year 2.3% of households, or over 150 million people, suffer healthcare expenses that cause financial catastrophe or impoverishment. The poorer the country, the worse the problem.

The proposed technology will enable more affordable healthcare through more cost effective manufacturing of biopharmaceuticals.

Biopharmaceuticals are drugs obtained from living things by using biotechnology. They have been proven in many cases to be more effective than conventional chemical-based drugs. Regulators in Europe and the US have already approved a drug derived from the milk of transgenic goats – Interestingly, the product, called ATryn, referred to this morning by Dr Jimmy Suttie, is manufactured in the USA using a herd which includes New Zealand goats.

AgResearch's current proposal is intended to both expand the **range** of biopharmaceuticals and **manufacture them in a more cost-effective manner**, leading to greater savings and improved health outcomes for New Zealanders and the global community. The comment that cheaper health products are not important ignores the increasing urgency surrounding the international healthcare crisis.

## **Jobs and added value into the NZ bioeconomy**

Science and technology, and the development of new products and processes, are essential to the creation of jobs, increased productivity and economic growth for New Zealand. If this application is not approved New Zealand jobs and new export products will not be created and New Zealand will miss out on a significant market opportunity and economic benefit. The OECD predicts that biotechnology will **add** over 350 billion New Zealand Dollars [240bn USD AT EXCHANGE OF 0.68 IS 382bn] gross value added to the economies of OECD countries by 2030.

Currently, around 14% of all new drug approvals each year are biopharmaceuticals. Improved and more cost effective production of biopharmaceuticals is a value added activity that addresses a large global market and will contribute significant value to global economies.

If these technologies and products are developed here in New Zealand, where we have significant expertise, by New Zealanders, then New Zealand benefits. Through the creation of jobs, firms, exports and income, such technologies and products are essential to our future wealth and prosperity.

In 2009 a BERL study concluded that in New Zealand, for every job created in the biotechnology-based sectors another 2.41 jobs are created in the broader economy. In addition direct spending of \$1 million in the industry generates a further \$1.03 million of gross economic output, and for every \$1 million of GDP generated, a further \$950,000 of GDP is generated in the broader economy. The successful undertaking of this research will generate a snowball effect, creating jobs, GDP and economic activity.

There is every reason to believe that AgResearch will be successful. Currently in a position of international leadership, AgResearch have spent many years of research in animal genetics and related areas. However, unless they are able to move this research forward and build on this world class expertise, their international competitive advantage will be lost, and the scientists will be forced to look to take their talent to other countries.

## **Failure to approve the work with appropriate controls sends an anti innovation message to researchers, research organisations and business**

Already the debate regarding genetic technologies in New Zealand has created enough uncertainty to drive work off-shore where a more stable operating environment exists. This means that kiwi funds are being spent on overseas jobs and research costs, because the environment in NZ is viewed as being volatile and uncertain for this type of product development. This uncertainty limits New Zealand's ability to attract talented kiwis and foreigners to our shores to undertake their work, limits enterprise creation and acts as a strong disincentive to investment.

As an illustrative example, one of our members has given up conducting trials of their genetic technologies in New Zealand:

They have support for their research from the end-users, from government and from farmers, and consumer research shows that their technology is, on the whole, acceptable to the New Zealand public. However, they are still doing their trials overseas, increasing the costs of the trials and resulting in significant lost benefit to New Zealand. Overall, the need for companies to take their work offshore reflects badly on the ability of New Zealand to be innovative.

The reason for this is **not the regulatory agency or the regulatory process per se**, but in New Zealand the amount of public debate and sensitivity to each individual application, the emotive, non-evidence based arguments that are often used by anti-genetic-technologies groups, and the resulting prolonged timeframes and high cost of trial approval.

Our ability to support our social structure and way of life is becoming hamstrung and those in our community with the knowledge, skills and expertise, our scientists, that have the ability to contribute significantly to the health and wealth of New Zealand and New Zealanders are becoming increasingly frustrated. This is completely counter to the Government's message that New Zealand must rely on innovation to close the widening income gap with other OECD countries.

**It is wrong to assume that the general public don't want GM. Public opinion on GM is fluid and certainly sees value in coexistence.**

Not much can be done to satisfy a deep philosophical opposition to co-existence of GM and non-GM in New Zealand. However, such views are in the minority. Independent consumer research has shown that the view of the public is much more sophisticated. The general public accepts GM when they can understand the application and see the benefit.

Marketing researchers from the University of Otago have done some very interesting experiments on consumer choice and GM. In one experiment random consumers at a roadside stall in the South Island were given the choice of GM spray-free cherries, low residue non-GM cherries, or Organic Cherries: 59% of people chose the GM cherries when they were 15% cheaper than the normal cherries.

The same researchers also studied actual purchasing behaviour in overseas markets. They found that simply growing GM crops in a country had negligible negative impact on the perception of the non-GM food from that country. Thus, it appears that the assumption that New Zealanders will not eat GM food and that our clean-green image will be tarnished by GM work in this country, **is not upheld by research focused on actual purchasing behaviour**. The researchers reached two highly pertinent conclusions, I quote:

*"..even in a country like New Zealand where there has been very vocal opposition to GM crops, a significant proportion of consumers will choose the GM option provided there is a clear consumer benefit ("spray-free") or lower price."*

*"GMO applications in non-food areas seem unlikely to impact on perceptions of country of origin image in relation to food products."*

Many consumers have far greater concerns than GM, such as the use of chemicals and environmental sustainability.

It is important to be aware that public sentiments can change rapidly as information becomes more available and easier to understand. The voices of vocal minorities do not always reflect the perception of the general public, which is often more sophisticated than they are given credit for. As with all new technologies, consumers need to be given time and information to adapt to what can be quite radical changes to the status quo.

## **Containment controls are sufficient and robust**

This work will be done entirely in containment. Thus the real risk is whether breach of containment is likely to occur, and if it does what the impact is likely to be.

It is the job of the government agencies such as ERMA, to use their expert advisors and go through the technical details of risks and mitigating controls. Those of us, like myself, who are not scientists nor technical experts, don't have the ability to appropriately assess technical risk. As such, NZBIO supports the analysis and opinion of the technical experts, including Dr William Rolleston who we heard from today.

Those that are qualified to understand the technical risks have done so and found that the controls are sufficiently robust. NZBIO supports their view and believes that the containment provisions are sufficient and the risk posed by a breach of containment is not significant.

We also see no risk to New Zealand's trade status or the image of New Zealand products. This work, being early stage development, is entirely separated from any commercial product at this stage. Also, we have seen from the consumer research, consumers can accept GM technology when properly informed.

**NZBIO believes that the potential benefits of the proposed research far outweigh any perceived risks. NZBIO supports ERMA in approving the application**

In summary, NZBIO sees significant social, economic and environmental benefits:

- **Environmental and trade benefits to NZ through Control over how these technologies develop**
- **Social benefits, globally, through better and cheaper healthcare**
- **Economic and social benefits to NZ through jobs and added value into the NZ economy**
- **Economic and social benefits for NZs future through support of an innovation capability and culture.**

The work will be done entirely in containment, with appropriate control to mitigate all foreseen risks.