### 7.2.1 Managing the return on the public's investment

A considerable, yet largely indeterminable, amount of public money has been spent on GM research and development in the outdoors. The majority of public investment in this technology has been through CRIs, which receive 'core funding' annually from the government and can also access additional research funding from MBIE for specific projects ('contestable funding').

In addition, CRIs generate revenue from private or commercial sources. For example, in the 2011/12 financial year, AgResearch's total revenue was $158 million, of which the government contributed $64.5 million ($38.8 million was core funding and another $25.5 million was additional funding from MSI – now MBIE – for specific projects) (AgResearch, 2012b; AgResearch, 2012c). Determining how funding is distributed and for what purpose is complicated. We know that, in 2011, $1.2 million of MSI funding was specifically allocated to AgResearch's transgenic livestock programme under contract number C10X0805 (see number 25 in Appendix 12); however, this is not necessarily an indication of the total cost of this programme.

The Institute encountered similar problems when researching these issues in 2008. For example, in that year, amid debate surrounding AgResearch's application to extend its GM livestock programme, Dr Jim Suttie, the programme leader, stated that since 1999 around $30 million had gone into the programme, including $1.5 million a year from FRST (equivalent to MSI funding discussed above) and $500,000 a year from private international companies (Fox, 2008). Going beyond this broad media statement and determining the actual cost of the programme to the public is not possible.

As it is the public who ultimately own CRIs, fund their investments and absorb the risks associated with these outdoor experiments, the public should be able to assess the value of their investment. Understanding value in this area relies on being able to determine how much public money has been spent on GM research and development in the outdoors, which is currently very difficult to do. From our understanding, such an exercise would require the following financial data specific to outdoor experiments since 1998:

- Cost of the Royal Commission on Genetic Modification: the Commission was provisionally estimated to cost $4.8 million (Hobbs, 2000), however the total cost amounted to over $6 million ('Commission rejects GM-free NZ', 2001).
- Net operational costs of ERMA/EPA in processing outdoor GM applications – see Appendix 12, Table 13, column (c).
- Operational costs of ERMA/EPA paid by applicants to ERMA/EPA – see Appendix 13, column (d).
- Operational costs of MAF/MPI in developing policy and enforcing regulations – not available.
- Share of CRI core funding allocated to outdoor GM research and development – not available.
- Contestable funding from FRST/MSI/MBIE allocated to specific outdoor GM projects – not available.
- Cost of litigation to ERMA/EPA which has been party to a number of court cases relating to GM applications (see Appendix 7).

To date, a large majority of outdoor experiments have been undertaken by CRIs with international partners. In practice, this means public money is used to co-invest in science for private benefit, meaning the benefits might go overseas while the risks stay in New Zealand. The Prime Minister's Chief Science Advisor, Professor Sir Peter Gluckman, has commented on this conflict between public and private interests:

> In some cases, however, CRIs have entered into contracts with the private sector that limit their capacity to give such advice (e.g. around land use), and indeed they can find themselves being contracted to give advice

> contrary to the Crown's wider interest. In general, entry into such contracts is often unwise and academia has shown them to be unnecessary. Academia enters into many private sector contracts and yet essentially none limit institutional ability to publish, subject to IP protection. On the basis of the now altered expectation of the CRI's, they must now take greater care in future arrangements to avoid compromising their ability to serve the crown as important and independent advisors. (OPMSAC, 2011: 14)

Section 5 of the Crown Research Institutes Act 1992 makes it quite clear 'that research undertaken by a Crown Research Institute should be undertaken for the benefit of New Zealand'. While the benefits of GM remain unproven and uncertain, at the very least, transparency over the size, ownership and return on the public investment to date should be paramount.

Those who have strongly supported GM research in New Zealand seemed to assume that benefits to a CRI equate to benefits for New Zealand. As one group of researchers noted in 2009, 'Benefits claimed for scientific research not yet carried out are necessarily speculative to some degree. However, this does not mean that these claims should not be thoroughly scrutinised' (Goven et al., 2009: 48). They went on to note that in ERMA's 2002 decision to approve AgResearch's application to biopharm cattle it was argued that as a reputable research institution AgResearch would be unlikely to pursue research without assurance of benefit, and that as a CRI these benefits would accrue to New Zealand. The researchers, however, found this argument unsound, noting: '... given the current structure of the science sector in New Zealand, it cannot be assumed that benefits to a CRI, even if these are realistically anticipated, equate to overall benefit to New Zealand' (Goven et al., 2009: 49).

Adequate scrutiny is imperative for New Zealand, especially in the case of biopharming, the use of genetic modification to produce biological compounds of pharmaceutical interest. If we are going to pursue the development of GM proteins for medical use through transgenic animals, this should be done with the utmost caution and scientific scrutiny. Further, one would expect medical experts to be involved and ideally driving the research, in terms of both the best process and the best organisms (animals, plants or microbes). Most importantly, the research must be market-led (e.g. it must be shown that such proteins are needed). One would also expect an explanation of why other methods such as indoor stainless steel fermentation vats might not produce better-quality proteins that are more likely to gain FDA approval for use.[37] Without due diligence, such research fails to fulfil the standard to be expected in a country that purports to undertake evidence-based research and spend its taxpayers' funds in a considered and effective manner.

In the late 1990s and early 2000s – at the height of the GM debate – AgResearch gained approval in 2001 for the use of transgenic cows to produce a protein (MBP) that could potentially help sufferers of multiple sclerosis. However, the possible benefits from creating MBP were never analysed by ERMA.

In making its 2001 decision, ERMA accepted that the principle benefit of the experiment was the scientific knowledge to be gained, stating that the significant benefits identified for assessment and evaluation are as follows:

> Benefits of scientific knowledge arising from the carrying out of the research (in accordance with clause 9(b)(i); 9(c)(v).) (ERMA, 2001a: 10)

In 2002, ERMA assessed benefits of a similar AgResearch application as follows:

> Benefits of scientific knowledge arising from the carrying out of the research including the acquisition of new skills (in accordance with clause 9(b)(i) and 9(c)(v)). [and] The applicant and others made reference to the

37 While the US Food and Drug Administration (FDA) only has jurisdiction in the US, globally, researchers see FDA approval as an important benchmark.

> specific downstream economic and health benefits to be gained from the products that might result from the commercial use or release of the genetically modified cattle. These products might especially include biopharmaceuticals. **The Committee did not consider these downstream benefits to be relevant to this application**, because it was for scientific development and not for release or commercial production. [Bold added] (ERMA, 2002a: 13-14)

In 2010, ERMA assessed benefits of a further AgResearch application as follows:

> 6.2.80 The Committee considered that the benefits of this research will primarily be in the form of increased scientific knowledge and skills enhancement. The Committee acknowledged that **FRST has made an ongoing investment of $8 million in the research programme over the next five years**. This funding will employ eight full time staff members, each of whom will gain knowledge and experience as a result of this work. Taking this into account the Committee considered the magnitude of this effect to be moderate.
>
> 6.2.81 The Committee also considered that this research may enhance New Zealand's reputation in the international science community. The Committee noted that the applicant's programme of genetic modification of animals has been operating successfully since 1998 (under previous approvals from the Authority). As this previous research has resulted in several articles in internationally recognised publications, and has attracted international commercial partners, the Committee considers the likelihood of realising this benefit from the research to be highly likely.
>
> 6.2.82 Therefore, the Committee considered that the measurable benefit of this research is the increase in scientific knowledge and the capacity for innovation in New Zealand. This level of benefit has been assessed as medium. [Bold added] (ERMA, 2010a: 34)

These decisions raise uncertainty around the scope of benefit assessment. Firstly the extent future benefits can be taken into account when balancing benefit with risk and costs, and secondly the extent that government investment can be used to demonstrate the existence of benefits. The Institute is of the opinion that when the EPA assesses potential benefits of an application as per s 45 of the HSNO Act, the fact that the experiment has previously received government funding must not be used as evidence that public benefit exists. The purpose behind a decision to fund a research work programme is significantly distinct from the purpose of decisions made under the HSNO Act.

Every scientific experiment provides knowledge; the real question is how much knowledge and to what end. The narrow assessment of benefits creates a process that we consider was not the intention of the legislation. Many considered that purporting this research as a possible cure for MS was simply PR spin to gain public support for the experiment. There was little evidence that this protein would successfully prevent symptoms of MS, or that its production through transgenic animals was necessary. Professor Lawrence Steinman, an MS specialist at the University of Stanford School of Medicine, noted in 2001 that 'Human or cow MBP can easily be made in bacteria or other microbes by fermentation. There is no need to produce it in cows at present' (Fitzsimons, 2001). See discussion in Section 6.1.

Any review of the HSNO legislation should consider whether benefits, as they currently sit within the legislation, provide a true weighing of benefits, costs and risks; and if whether the analysis of benefits should be extended to include longer term considerations. See discussion in Section 7.2.12.

As Jeanette Fitzsimons, co-leader of the Green Party, noted at the time:

> AgResearch is not a medical research institution. It has absolutely no experience in multiple sclerosis, neurology or base myelin protein. It is involved in agricultural research and the purpose of this project is

> to try to use cows to manufacture bulk quantities of a protein. That is where this project will stop. There is no indication who, if anyone, will then do the clinical work with that protein to see if it is useful and if so, develop a drug. (Fitzsimons, 2001)

This brings us back once again to the question of value. If the public is going to be asked to invest significant amounts of money in scientific research, it must be with the assurance that the benefits are adequately scrutinised and will accrue to New Zealand.[38]

In 2013 Professor Sir Peter Gluckman stated that '[a] worrying feature of the New Zealand science system is that, compared to other participatory democracies, there is a relative lack of process and investment surrounding the development of objective evidence to support policy formation' (OPMSAC, 2013: 7).[39] He went on to note that:

> … the quality of policy programme assessment and evaluation is often not rigorous. Such scrutiny can be compromised or biased by agencies not wanting to embarrass the owners of a political decision. The evaluation process can be seen as unnecessary, especially where rhetoric has led to a strong political position. In general the understanding of the components of programme evaluation is weak across many agencies … [and]
>
> Part of improving the use of government funds is also to improve the focus and commitment to programme evaluation. Ministers should expect and demand that more programmes are subject to efficacy evaluation, that funds are allocated for that purpose, and that reviews consider not only new programmes as they are rolled out, but where possible current programmes. There should be no political embarrassment in acknowledging that the impact of a new programme is not known and must be evaluated. (OPMSAC, 2013: 7, 9)

**Recommendation 1: Investment programmes should be evaluated as a matter of good practice**

Investment programmes developed by the government (including CRIs) that are particularly risky, contentious, involve joint ventures and/or represent a significant investment of public funds, should be regularly assessed. The government should do this as a matter of course; however, what the Institute recommends is significant improvements in transparency. Published reports should be prepared regularly, identifying the aim of the project, primary goals, key stakeholders (including relationships such as joint ventures/partnerships), past and perceived benefits (in particular, clarity over who owns the benefits of the investment programme), costs (in particular, the size of the public's investment) and a full assessment of all known and potential risks (including investment, financial, legal liability and environmental risks).

### 7.2.2 Managing risk

Risk management is a fundamental part of managing any new scientific tool. With any tool it is about best practice: when to use the tool, when not to use it, and how to know the difference. Genetic modification is a great example of a tool that demands answers to these questions, a point not lost on Sir Peter Gluckman, who said the following in a 2012 blog post titled *Dialogue or direct action?*

> But at the heart of that dialogue is a complex interaction that can be summed up in three words: 'understanding of risk'. Risk means different things to different people – scientists may talk in mathematical probabilities; politicians think of risk in an electoral sense; the public generally sees risk through a lens that

38 Interestingly, the dairy industry in Australia has discontinued investment into all transgenics, see Section 7.2.10.

39 It should be noted that in his role as Chief Science Advisor Professor Gluckman has never stated explicitly whether he supports or opposes GM research and development in food production; rather he emphasises governance issues such as the need for effective communication between the public, scientists and government, risk management and evidence-based decision-making.