7.2.1 Managing the return on the public's investment

Understanding the consequences of the public's investment in 'GMOs in the outdoors' requires an appreciation of the way government shapes regulatory systems and utilises those same systems to undertake outdoor GM research. This section looks firstly at the decision *to invest* and then at how benefits are analysed in the decision *to approve* an application.

1. The decision to invest

Public funds are used to invest in regulatory systems and research experiments. New Zealand invests in GM through the creation and management of regulatory systems and investment in research. Trying to understand the financial investment New Zealand has undertaken to develop a GM strategy and design appropriate regulatory systems poses a significant challenge. Such an exercise would require a great deal of financial information, much of which is not available, for example:

- The 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).[36]
- The cost of strategy development, such as the 2003 report on biotechnology – not available.
- The operational costs of ERMA/EPA in processing outdoor GM applications – see Appendix 12, Table 14, column (c).
- The operational fees (revenue) paid by applicants to ERMA/EPA – see Appendix 13, column (d).
- The operational costs of MAF/MPI in enforcing regulations and providing assurance – not available.
- The cost of inquiries into breaches undertaken by MAF/MPI (see Appendix 14) – not available.
- The cost of cleaning up breaches found by MAF/MPI – not available.

In addition, a considerable, yet largely indeterminable, amount of public money has been spent on outdoor GM research, in terms of developments and field tests undertaken by CRIs. CRIs not only receive 'core funding' annually from the government but are able to access research funding from MBIE for specific projects ('contestable funding'). Government funding of CRI's is allocated for broad research programmes, one aspect of which may involve GM research. Therefore initial funding is often allocated months and sometimes years before an application to develop or field test a GMO in the outdoors is considered. The impact of this is discussed in point 2 (below).

Ultimately it is the public who own CRIs, fund their investments, and absorb the risks associated with outdoor experiments. The public should therefore be able to assess the value of their investment. Such an assessment is dependent on transparency in relation to how much public money has been spent on GM experiments in the outdoors, which is currently very difficult to determine. To understand how much the New Zealand public has invested in outdoor GM research would also be difficult. Such an exercise would require a great deal of financial information, much of which is not available, for example:

- Share of CRI core funding allocated to outdoor GM research and development – not available.
- Contestable funding from FRST/MSI/MBIE/Callaghan Institute allocated to specific outdoor GM projects – not available.
- Cost of litigation to ERMA/EPA/CRIs, which has been party to a number of court cases relating to GM applications – not available (see Appendix 7).

Although determining the full extent the New Zealand public have invested in GM research in the outdoors is difficult, we do know is that the Crown's investment has been significant. Since 1988, 42% of

36 It is unlikely a Royal Commission would have been necessary if New Zealand had decided to remain GM free in the outdoors.

commenced outdoor research experiments have been undertaken by CRIs.[37] Further, the only outdoor experiments being undertaken today are by two CRIs – AgResearch and Scion; currently no private firms are undertaking outdoor GM experiments.

A further complexity is the conflict that may exist where CRIs have obtained revenue from private and 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; 2012c). Determining how funding is distributed and for what purpose is complicated. For example, 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 the programme. To date, a number of outdoor experiments have been undertaken by CRIs with international partners. For example, AgResearch negotiated a joint venture with Scottish company PPL Therapeutics, stating that its successful completion 'will result in the creation of a New Zealand business worth approximately $50 million' (Atkinson, 2002). In practice, this means public money is used to co-invest in science for private benefit. Co-investing with the private sector can have impacts on the extent that benefits for the public exist, and the reality may be that the benefits materialise overseas while the risks stay in New Zealand. Further, this may impact on the CRIs' ability to meet their public good obligations. 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)

2. The decision to approve

Since 1988 there have been three different approving agencies for outdoor GM experiments; IAG, ERMA and now the EPA. The 1996 HSNO legislation established ERMA, who would be responsible for applying the methodology. This applies both generally (the HSNO Act 1996 states its purpose in s 4 as 'preventing or managing the adverse effects of hazardous substances and new organisms') and specifically, weighing positive effects against negative effects.[38] The latter might include, for example, *containing a GMO* ('the beneficial effects of having the organism in containment outweigh the adverse effects' – see s 45 of the HSNO Act 1996), *importing or releasing a GMO without controls* ('the positive effects of the organism outweigh the adverse effects' – see s 38 of the HSNO Act 1996), and *importing or releasing a GMO with controls* ('the positive effects of the organism outweigh the adverse effects' – see s 38C of the HSNO Act 1996).

In the past, ERMA has generally considered that outdoor GM research will provide benefits in the form of scientific knowledge, and that the existence of such knowledge should be assessed as 'high'.[39] However,

37 Of the 70 outdoor experiments applied for, only one experiment was declined by the Interim Assessment Group (IAG) in 1991 (see Appendix 9). Further, of those 69 experiments, six were withdrawn by the applicant before being decided by ERMA. Of the 63 remaining, six (although approved) were never implemented three of those were CRI approved experiments. This is how the figure of 57 approved and commenced outdoor experiments shown on page 6 was generated. In terms of CRIs, 24 of the 57 (42%), represents the percentage of outdoor research experiments implemented by CRIs in New Zealand since 1988. In addition to these 24 CRI experiments, 12 experiments were completed by the former Department of Scientific and Industrial Research (DSIR) and four by universities, meaning about 70% of approved and commenced outdoor experiments have received some form of public funding.

38 We understand this is quite novel internationally; most other regulatory authorities only assess risks, not the costs and benefits of applications.

39 (see reference below to AgResearch's 2010 application, and ERMA's assessment that 'This level of benefit has been assessed as medium')

ERMA's decisions do not explain the basis upon which such assessments are made, and applications tend not to disclose benefits for reasons of commercial sensitivity. Further, in the case of applications by CRIs, ERMA considered that if something is publicly funded public benefits must exist.[40] Additionally, the ERMA committees who made such decisions usually did not have the commercial skills necessary to make assessments on commercial benefit. To explain how this lack of scrutiny shows itself in previous decisions by ERMA, we draw on the following example.

In 2001, AgResearch gained approval for the use of transgenic cows to produce a protein (MBP) that could potentially help sufferers of multiple sclerosis (see discussion in section 6.1). However, the possible benefits from creating MBP were never fully assessed by ERMA. In making its 2001 decision, ERMA accepted that the principal benefit of the MBP cows experiment was the scientific knowledge to be gained, stating that the significant benefits identified for assessment and evaluation were as follows:

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

In 2002, ERMA assessed the 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)). … The applicant and others made reference to the 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 the benefits of a further AgResearch application:

> 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)

40 Under the Crown Research Institutes Act 1992 (s 5), a CRI must operate according to the principles that all research should be undertaken 'for the benefit of New Zealand' and that 'a Crown Research Institute should be an organisation that exhibits a sense of social responsibility by having regard to the interests of the community in which it operates and by endeavouring to accommodate or encourage those interests when able to do so'. See also Section 6 for the full text of s5.

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, found this argument unsound, noting that '... 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' (ibid.: 49).

Every scientific experiment provides knowledge; in this context the question is the value of that knowledge, how it is gained and how it might be used. There is little value in assessing benefits so abstractly that they cannot be considered in terms of the related costs and risks. In contrast, a similarly vague assessment of risk would likely be unacceptable in the decisionmaking process. For example, in contrast the committee would not argue that this research may risk New Zealand's reputation in overseas markets, and rate that risk as medium. The level of scrutiny should be equivalent for all; benefits, costs and risks.

Furthermore, the assumption that Crown funding is evidence of the existence of benefits for the public good is highly questionable. The Institute is of the opinion that when the EPA assesses the potential benefits of an application (as per s 45 of the HSNO Act 1996) the fact that the experiment has previously received government funding should not be used as evidence that public benefit exists. The purpose behind a decision to fund a research work programme is significantly different from the purpose of decisions made under the HSNO Act 1996.

Taken together, the points discussed above reinforce the importance of ensuring that decisions regarding the investment of public money (such as MBIE, MPI and the Callaghan Institute) and the weighing of positive and negative effects (by EPA) are sound. These decisions require separate processes; decision makers charged with making effective decisions to invest public funds have a very different purpose than those charged with making effective decisions to approve specific outdoor GM experiments or releases. If MBIE allocates public funding to a research programme that at some point in the future may involve GM approval under the HSNO Act 1996, they are not providing evidence that public benefits exist in regard to that GMO. That assessment can only be undertaken by the regulatory authority, the EPA; they are the body tasked with scrutinising effects, and then weighing these effects in order to make the best decision New Zealand.

The importance of improving the quality of assessment and evaluation should not be underestimated for a country whose reputation is so tightly aligned with food quality. 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).[41] 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 ... 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,

41 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 decisionmaking (OPMSAC, 2013).

> 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. (ibid.: 7, 9)

The above discussion raises a number of questions for further consideration:

- What is the true cost to the public of maintaining a strategy of GMOs in the outdoors?
- What is the return on the public's investment of CRIs undertaking outdoor GMO research?
- To what extent should benefits be scrutinised; both in terms of the potential scientific knowledge gained and justice – who benefits from this knowledge as compared with who bares the harm if risks occur?
- If outdoor GM experiments are carried out by CRIs in joint ventures with private companies, who owns the resulting intellectual property? If the private company is overseas based and has control over those benefits, should not the overseas company's share be removed from the assessment by the EPA?
- To what extent should highly improbable future benefits be taken into account when balancing benefits with risk and costs? Importantly, the purpose of scientific research should not always be commercial, but if applicants argue that commercial benefits exist, they nevertheless should be scrutinised in terms of probability and magnitude.
- Is it acceptable for the EPA to argue that public good benefits exist because a government institution funding science research, such as MPI, MBIE or the Callaghan Institute, have agreed to fund a research programme?
- How can we evaluate and ideally improve the quality of assessment and evaluation in regard to investment decisions by the MBIE and the Callaghan Institute?
- How can we evaluate and ideally improve the quality of assessment and evaluation in regard to approval decisions by the EPA?

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, must be regularly assessed. The Institute would like to see significant improvements in procedural transparency. Integrated reports must be published regularly, identifying the aim of the project, primary goals, key stakeholders (including relationships such as joint ventures/partnerships), recognised 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). Any review of the HSNO legislation should consider whether the current arrangement allows a true analysis of benefits (see also the discussion in Section 7.2.12). If government is going to continue to invest significant amounts of money in a framework for CRIs to undertake outdoor GM experiments, it must provide assurance that the benefits are adequately scrutinised in terms of the benefits that will accrue to New Zealand, that costs are borne by the applicant (not the public) and that risks are well-managed. Further, we believe a register of all government funds, including grants and capital, should be made transparent to the public to ensure companies are not double dipping and to ensure the focus remains on the public's return from investment.