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# **The New Frontiers**

## **Biotechnology Liability Law Reform**

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## 1. The New Frontiers

The Royal Commission on Genetic Modification (the Commission)<sup>1</sup> labelled biotechnology “the new frontier”. Along with the potential benefits the Commission saw from ongoing development of biotechnology in New Zealand, it also reported sources of risk associated with this field of research, especially in respect of the release of genetically modified organisms (GMOs).

As an input to determining how Government should respond to these risks, one of the issues the Commission was asked to report on was whether the current laws governing liability were “adequate”. In light of the Commission’s overall view on genetic modification - that “we should go forward but with care”<sup>2</sup> - it was all the more important that the Commission provide a thorough review on this question.

Its work in respect of liability issues however was not a thorough review. The Commission did not put forward the required analysis to support its recommendation that there be no change to the existing liability regime. The practical effect of the Commission’s recommendation would be to socialise some of the riskiest aspects of biotechnology. This is acknowledged in the conclusion to Chapter 12:

We appreciate this means there is some potential for some socialisation of unforeseen or unanticipated loss or damage ...<sup>3</sup>

As the Commission observes, the more unforeseen and unanticipated the loss, the more it will be socialised. Thus responsibility for the contingent liabilities associated with unforeseen and unanticipated losses would rest heavily with individual citizens and businesses.

The Commission did however suggest Government may wish to get further opinion on the issue and this began a new phase of investigation, results from the first stage of which were announced last week.

## 2. Back to first Principles

Investigation of what form liability law should take involves tackling the parallel “new frontiers” in public policy that have emerged in response to technologies such as genetic modification which represent a new class of environmental risk.

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<sup>1</sup> The Royal Commission on Genetic Modification was appointed in May 2000 to advise the New Zealand Government how to respond to the complex set of policy issues biotechnology research and application raises. It reported in July 2001.

<sup>2</sup> Ibid.

<sup>3</sup> Ibid, p. 328.

GMOs have particular characteristics from the risk point of view that mean the potential damages can be very high. One of the main ones is the ability of GMOs to self-perpetuate. As a toxic spill involves a defined amount of a particular substance, the cleanup is a matter of attending to a known and finite quantity of material. However, a GMO may well have the ability to self-perpetuate without limit. Thus, GMOs pose a level of potential clean up cost that is not readily subject to pre-estimation.

Dr David Suzuki, a geneticist by training and a leading international ecologist, summed up this picture in his witness brief to the Royal Commission as follows:

The difference with this technology is that once the genie is out of the bottle, it will be very difficult or impossible to stuff it back. If we stop using DDT and CFCs, nature may be able to undo most of the damage – even nuclear waste decays over time. But GM plants are living organisms. Once these new life forms have become established in our surroundings, they can replicate, change and spread, so there may be no turning back.<sup>4</sup>

The key function of a liability regime is to determine who bears the risks of a particular activity. There are a number of reasons for defining a liability framework in advance of risky activities being entered into. Two basic motivations are:

- To establish clear accountability, so as to incentivise the parties undertaking a risky activity to take due care; and
- To allow involved parties to better define their potential exposures to harm and/or damages, and thus be better placed to insure or in other ways protect their positions.

Three objectives should guide design of liability law:

- i. Provide compensation for victims;
- ii. Incentivise operators to take due care;
- iii. Provide correct economic incentives for investment.

These objectives are addressed in the following principles the New Zealand Government committed to through the Rio Declaration in 1992, and recommitted to last year:

“13. States shall develop national laws regarding liability and compensation for the victims of pollution and other environmental damage. ...”

“16. National authorities should endeavor to promote the internalisation of environmental cost and the use of economic instruments, taking into account the approach that the polluter should, in principle, bear the cost of pollution ...”

It is clear that principle 13 targets the first objective, compensation for victims, and this goal is uncontested.

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<sup>4</sup> Commission Report, p. 55.

Principle 16 advances the “polluter pays” principle and in doing so covers the other two objectives. It relies on financial disciplines incentivising “correct” behaviour. This includes both due care and an optimal level of investment. It is a market mechanism for simultaneous delivery of objectives 2 and 3.

The appropriateness of the second objective, incentivising operators to take due care, is (like the first objective) uncontested. The New Zealand debate, more so than in other jurisdictions, seems to centre around the third objective of providing correct economic incentives for investment.

### **3. Incentives for Investment**

A general principle in the economics literature is that, wherever possible, economic agents should both (i) be able to appropriate at the margin the economic value which they create, and (ii) face the full marginal costs of their activities.

Unless firms face the full marginal social costs of their activities, they will have the incentive to over-expand those activities at the cost of the wider economy. In the limit, this may mean that activities which ought not to be undertaken at all – and which would not be undertaken if those responsible had to bear the full costs – can be privately profitable. The process of “internalising” costs which otherwise would fall on third parties is a necessary precondition if market mechanisms (that is, voluntary transactions among private parties) are to lead to socially efficient outcomes.

GM will in general be just one means to a particular outcome that is being sought. Whether the objective is higher crop yields, stronger wood, or better medical cures, GM will be just one means to the end. To the extent the full costs of the activity are not internalised, GM production routes are being subsidised. They are being given an undue advantage over other potential solutions.

Claims for damages resulting from use of GMOs form part of the full cost of selecting GM technology to meet a particular objective. Those full costs will only be known ex post. However, when this risk is transferred to a third party, the consideration paid to the insurer or broker then represents the best present day estimate of the risk weighted cost.

By paying for the present day cost of the risk, the GM operator is internalising that cost. If the operator does not pay that cost, it does not go away. It sits with either the taxpayer or the victim, depending on the circumstance. They may not pay an insurance premium today, but they are implicitly carrying a contingent liability on their accounts.

So rather than insurance premiums “equat[ing] to a penalty on a particular activity or product, disadvantaging those wishing to trade in the field”, as the Royal Commission put it, insurance represents an opportunity to shed risk and quantify costs that are already present. Only by arguing that insurance costs should be socialised, not internalised, could premiums be described as a “penalty”.

If we compare two projects of “equal riskiness”, with one of them a GM project and the other non-GM, and if both projects face liability regimes that are appropriately designed to ensure compensation for injured parties and to incentivise the taking of due care, then there is no presumption that the resulting investment decisions are “inefficient”.

The Ministry for the Environment (MFE) discussion paper that canvassed options for reform of the HSNO Act in respect of liability law stated that:

“It would clearly be counter-productive to design liability rules that provided full compensation in all eventualities, if the practical consequence was that the costs and risks of engaging in the activity were prohibitive. Liability rules must fit with the basic goal of preserving opportunities.” (p59)

“Preserving opportunities” does not and should not mean sustaining socially uneconomic opportunities through subsidies, whether those subsidies are funded by taxpayers or by shifting risk onto innocent members of the public. If an economic activity can not itself sustain the full costs which it imposes on society, then it should not be undertaken. Obviously, if there are benefits as well as costs that are external to the firm, such that overall its activity is socially beneficial, there may be individual cases that merit individual subsidy. However, there should not be a blanket subsidy in this respect.

The willingness of both the Royal Commission and the MFE discussion paper to contemplate such blanket subsidies, via potential relief of GM firms from full liability for the costs their activities impose on society, is not supported by reference to any established principles. A subsidy arrangement would be inconsistent with New Zealand’s international commitments under the Rio Declaration, and with the standard minimum requirements for economic efficiency in the dynamic as well as the static allocative sense.<sup>5</sup>

This is not to say that Government should never subsidise an activity that is unprofitable. The argument is simply that if Government wishes to pursue a particular policy of industry assistance, the assistance should be transparent by way of explicit subsidy and Government should be fully accountable for the decision.

#### **4. Strict Liability**

The two fundamental institutional mechanisms for internalising and pricing contingencies are (i) legal liability for damage, and (ii) insurance.

Legal liability is the key component of a policy package to internalise the costs of genetic modification (GM). The prospect of having to compensate any third parties who suffer future damage provides an immediate incentive for GM firms to act with

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<sup>5</sup> That is, a general subsidy would subvert the efficient choice of investment projects by private agents, because the profitability of GM projects would be artificially raised relative to the returns available from normal competitive activities; and it would subvert the efficient allocation of society’s scarce resources by diverting them from more socially-profitable activities into the subsidised GM activity.

due care in relation to matters such as containment procedures, thorough pre-release testing, and non-development of particularly high-risk and/or high-damage aspects of the technology.

An extensive economic literature<sup>6</sup> supports the application of strict liability in circumstances such as those prevailing for GMO development. Under strict liability the firm is responsible for the full future consequences of its actions, whatever those consequences may turn out to be, and regardless of whatever precautions it may have taken to minimise the risk of accident. This is in contrast to the negligence standard - which is implicitly built into the HSNO Act in its present form. Under a negligence standard of liability, the firm faces penalties only if it fails to act in accordance with predetermined standards of behaviour; compliance with those regulatory requirements is therefore sufficient to provide a legal defence.

Use of a legal liability approach based on negligence will fail to signal correctly to the GM firm the true potential costs of its actions. As Shavell points out,<sup>7</sup>

Under strict liability injurers bear risk and victims are protected against risk, whereas under the negligence rule injurers do not bear risk – if they are not negligent, they will not have to pay damages when involved in accidents – and victims do bear risk.... [S]trict liability will be attractive when injurers ... are better able to bear risk than victims...

Strict legal liability appears to be the key (albeit not perfect) means by which external costs arising from GM activities can be internalised.<sup>8</sup>

## 5. Financial Fitness

Irrespective of the nature of the law put in place to define an operator's liability, the question remains how to ensure there are funds actually available to provide compensation. As the Royal Commission noted, "The defendant may be a shell company without substantial assets, or may be insolvent."

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<sup>6</sup> For example Polinsky, A.M., "Strict Liability versus Negligence in a Market Setting", *American Economic Review* 70:363-367, 1980; Green, J., "On the Optimal Structure of Liability Laws", *Bell Journal of Economics* 7:553-574, 1973; Dewees, Donald, "Tort Law and the Deterrence of Environmental Pollution", in Tietenberg, T.H. (ed) *Innovation in Environmental Policy: Economic and Legal Aspects of Recent Developments in Environmental Enforcement and Liability*, Edward Elgar, 1992; Shavell, Steven, "Strict Liability versus Negligence", *Journal of Legal Studies* 9:1-25, 1980; Calabresi, Guido, *The Costs of Accidents: A Legal and Economic Analysis* Yale University Press, 1970.

<sup>7</sup> Shavell, Steven, "On Liability and Insurance", *Bell Journal of Economics* 13(1):120-132, Spring 1982, p.121.

<sup>8</sup> On the relevance of legal liability as a means of establishing contingent prices for accidents see, e.g., Shavell, Steven, *Economic Analysis of Accident Law*, Harvard University Press 1987; Segerson, Kathleen, "Liability and Penalty Structures in Policy Design", Chapter 13 in Bromley, D.W. (ed), *The Handbook of Environmental Economics*, Blackwell, 1995, pp.272-294; Brown, J.P., "Toward an Economic Theory of Liability", *Journal of Legal Studies* 2:323-339, June 1973; Russell, Clifford S., "Economic Incentives in the Management of Hazardous Waste", *Columbia Journal of Environmental Law* 13:257-274, 1988; Segerson, Kathleen and Tietenberg, Tom, "The Structure of Penalties in Environmental Enforcement: An Economic Analysis", *Journal of Environmental Economics and Management* 23:179-200, 1992;

No amount of law reform aimed at encouraging due care on the part of operators will be particularly effective without provisions that require financial fitness on the part of the operator. The incentives on an operator with little to lose are very different from those who are financially exposed to the full potential consequences of their actions.

At present, the HSNO Act does not empower ERMA to require a bond or other assurance that an applicant can meet any claims for damages. The Act instead places a heavy reliance on controls and penalties for breaching these. The problem with this approach is that the regulator must accurately foresee all the circumstances in which something could go wrong, and be able to prescribe for these in advance. However, an important source of risk now recognised in respect of GMOs is unexpected adverse effects. A liability regime based on “perfect” foresight is therefore ill-suited to these risks.

The required reform is that financial fitness be made a condition for securing ERMA consent for either experimentation or release of GMOs. Financial fitness would consist of proof of financial cover of the form and level required by ERMA for that project and a requirement to post a performance bond. The financial cover may be by way of traditional insurance or other risk transfer mechanisms. Different applications will carry different levels of risk and different financial cover packages will be appropriate.

Research in containment is relatively less risky and there is evidence that traditional insurers will continue to provide cover for reputable institutions and even that specialist insurers in environmental damage who cover GMOs are emerging in Europe.<sup>9</sup>

Applications for release pose higher levels of risk and there is evidence of reluctance by a great many traditional insurers. The Law Commission among others has tended to see traditional insurance as the sole mechanism by which financial cover may be obtained. In fact, insurance is just the most common and well known form of risk transfer mechanism.

One alternative is a new class of financial derivatives that emerged following major natural disaster claims in the mid 1990s. These instruments are generically known as “catastrophe bonds”. A catastrophe bond is a financial instrument which is issued and traded on capital markets in the normal way. It carries a coupon rate of return and a contingent liability that, in the event of occurrence of some specified catastrophe, the insurance costs of the event are deductible from the principal sum. Thus the investor assumes the insurer’s risk in exchange for a premium rate of return on the bond.

The cat bonds market developed in part because of evidence that catastrophe insurance and reinsurance contracts available from the traditional insurance industry were overpriced relative to the available evidence on actual losses, so that a profit

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<sup>9</sup> Agriculture and Environment Biotechnology Commission, Environmental Liability Development Group minutes, 20 December 2001. <[http://www.aebc.gov.uk/aebc/liability\\_meetings\\_201201\\_minutes.html](http://www.aebc.gov.uk/aebc/liability_meetings_201201_minutes.html)> 2–3.

opportunity existed. Billions of dollars in reinsurance capacity has been created using such capital market instruments.

Thus cover for GM release applications may well make use of alternative instruments to traditional insurance. Where the risks are supportable by financial markets, cover will be secured. If cover is provided to some GM release applications in this way but not to others, that is in principle a message that ought to be important in its own right in considering an application. If it means an application can not proceed because it has not met the minimum cover requirements, it is submitted that that is a sound basis for discrimination in addition to the consideration ERMA have applied.

If an applicant believes there is a strong national interest in developing a particular GMO for which cover can not be obtained, then it is always open to the developer to propose to Government that taxpayers should provide the balance of any liability cover over and above what the project promoter can secure from the market. The resulting contingent liability would then be clearly recorded in the Crown's balance sheet.

What is not acceptable is socialisation of the risks by default. Any arrangement that implicitly limits liability without determining how the remaining risk will be provided for means damages would tend to lie where they fall. Thus, to the extent any application is granted on the basis of only a capped level of cover, the Crown should explicitly underwrite the residual risk.

## **6. Reform to Date**

On February 12, the Government announced a series of proposals for amendment to the HSNO Act, including changes to the liability provisions in the act. The changes are a very disappointing response to a key public policy issue.

In essence, the status quo remains with the minor change that operators who breach ERMA controls, or break the law by acting without approval, become strictly liable for any harm caused. This replaces the current negligence standard. By making prosecution easier, through no longer having to prove negligence, the change does indeed deliver "incentives to comply with the regulatory regime, as full liability based on the amount of harm caused could result from failure to do so."<sup>10</sup>

However, this change fails to address the major areas of concern. In particular, it leaves untouched the negligence standard in respect of ERMA approved activities that result in harm. So long as the operator abides by the controls ERMA sets, it will only be responsible for third party damages under HSNO of proven negligent. Further is rejected any financial assurance requirements being set.

In advising against further liability law reform, Government officials advanced two layers of arguments.

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<sup>10</sup> *Government Response to the Royal Commission on Genetic Modification: Legislative changes for New Organisms – Paper 5: Liability issues for GM*, Cabinet Paper, February 2003, p 7.

The first was a general rejection of the need for reform on the basis that new organisms present no new liability issues. While conceding that “none of the relevant Acts provide for compensation for harm caused to private or public property”, the argument is advanced that “there are no unique liability issues raised by GM”.<sup>11</sup> Officials further concluded that “there does not appear to be a principled basis for devising a special liability regime solely on the basis of a GM/non-GM distinction”.<sup>12</sup>

This line of argument simply ignores any first principles assessment of the issues. It is the equivalent of - when asked the question “Do you know the way to Dublin” - responding that “I wouldn’t start from here”. The best time to set a principled liability and accountability framework is when the industry is being first established, as it effectively is now. The consistency is to be found in fully allocating costs from a new industry, not in pretending that change can only occur on a universal basis.

The second and more serious layer of argument provided explicit rejection of many of the measures discussed above that could contribute to the objectives for liability design. While the justifications are fleeting, they are quite revealing. The following examines each in turn.

### **Strict Liability**

“We ... do not support this option because it would be contrary to the government policy of proceeding with caution while preserving opportunities. Imposing the more stringent standard of strict (or absolute) liability may deter activities that are socially beneficial and, consequently, stifle innovation and economic growth contrary to government policy.”

As outlined above, this is conceptually flawed thinking. Delivery of national benefits (the kind referred to here) depends on a full costing to the nation, not just the party undertaking development. If a development is not commercially attractive when the full financial risks are counted, then that is not an “opportunity”. Effectively shifting the risks to other parties through operating a negligence standard sets up a subsidy arrangement. Again, Government may choose to individually subsidise particular projects. A blanket subsidy has no coherent rationale.

### **Compulsory Insurance**

“Compulsory insurance is not a viable option, as information points to insurance for GM harm not currently being available. It is also not clear whether insurers will be able to adequately monitor precaution taken by insureds and reflect it in the terms of insurance, by pricing to reflect risk and precaution, or by denying cover where certain forms of precaution are not taken. If insurers cannot do this, the cost of insurance is driven up to prohibitive levels and fewer people engage in the activity, or insurance becomes unavailable.”

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<sup>11</sup> Ibid, p 4.

<sup>12</sup> Ibid, p3 .

It is difficult to tell what information officials relied on to form their views about the viability of insurance options. The text gives a strong indication however that officials looked simply at one model of insurance availability – that of conventional retail insurance. In doing so, they appear to have overlooked the opportunities for self-insurance and capital market mechanisms for providing cover.

## **Bonds**

“Requiring the Environmental Risk Management Authority (ERMA) to consider imposing insurance or bond requirements, as a condition of approving release of a new organism to address liability concerns is not supported. Assessing when and how to use such discretion and the amount of any insurance or bond would, generally, be a highly speculative exercise. It would involve consideration of a range of difficult issues that ERMA may not be well placed to undertake. There is a risk that socially beneficial activities might be deterred and capital would be tied up when it could be put to more productive uses.”

Just why these problems are so acute in ERMA’s case when Regional Council’s have the power to require bonds under the RMA is a mystery. It is a matter of considerable concern that activities which, in general, are likely to be more risky than those approved under the RMA are not proposed to be subject to the lowest level of financial assurance requirements.

In summary, Government has failed to effectively address deficiencies in the current liability regime. The root problem appears to be a flawed analytical framework for what constitutes genuine “opportunity”. The haste with which the current policy reforms were developed is regrettable as this no doubt contributed to the poor results of this first round of policy work.

## **7. Key Messages**

What should industry take as key messages and future directions?

- Introduction of a polluter pays approach is a globally agreed goal. Different countries are proceeding at different speeds towards this goal but the trend is essentially one way.
- The extent of reform able to be contemplated in New Zealand has been constrained by the very tight timetable Government imposed on consideration of HSNO reforms.
- Companies will be best protected into the future by assessing projects as if strict liability was already the standard, and then assessing it under the prevailing law. This encourages analysis of sources of project risk and their potential magnitudes.
- In undertaking such analysis, project proposals can be better tested against alternative approaches in technology which may reveal less risky means of achieving the same objectives.