Who Bears the Risk?

Genetic Modification & Liability

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Executive Summary

The Royal Commission on Genetic Modification (the Commission) was established to advise Government on policy issues raised by genetic modification, including liability for any damage resulting from the development and release of new organisms. The Commission has not put forward the required analysis to support its recommendation that there be no change to the existing liability regime.

The function of a liability regime is to determine who bears risk. It is important to define a liability framework in advance in order to incentivise parties to take due care, and to allow involved parties to better define exposures and thus be better placed to protect their positions.

The Commission recommends no change to the existing law and acknowledges that the practical effect of this recommendation would be to socialise some of the most serious biotechnology risks. ("We appreciate this means there is some potential for some socialisation of unforeseen or unanticipated loss or damage … .")

In absence of a Crown or industry funded entity to be the risk bearer, such losses will fall on innocent parties (often third party citizens and businesses) and will remain with them unless they can persuade the government that it should assist.

Potential Liabilities

Genetically modified organisms (GMOs) are a new class of environmental risk. Environmental regulation was initially framed around rather visible sources of pollution that were ultimately biodegradeable. However, a number of technologies produce substances that are not readily broken down and assimilated into the natural environment. These represent quite different forms of risk to biological systems. Examples include nuclear materials and many synthetic chemicals containing chlorine.

New organisms, as a class, have also shown the potential to be hazardous. Thus, under the Hazardous Substances and New Organisms (HSNO) Act, all GMOs are presumed hazardous in the first instance.

Potential damages resulting from the release of GMOs into the environment that are likely to be legally actionable can be broadly grouped into the following three categories: damage to human health, damage to biodiversity, and economic loss (including property damage or economic loss resulting from GMO contamination).

The following types of damages claims could arise:

- *Personal Injury:* Allergenicity and toxicity are possible causes of personal injury through consumption of GMOs.

- *Effects on Non-target Species:* GM crops can have adverse effects on non-target species in the receiving environment. This might occur directly or indirectly, for example via the reduction of food resources the organisms depend on.

- *Invasiveness in the Environment:* increased persistence, intrusiveness and competitiveness with existing native or exotic plant species which could alter population dynamics and ecological balances.

- *Contamination and Gene Transfer:* transfer of genetically modified material to other crops, including contamination of organic crops and resulting processed foods.

- *Rare Events:* an incident that introduces consequences or effects of a disastrous magnitude in circumstances where the risk of occurrence was uncertain or not readily quantifiable (for example, BSE in the United Kingdom).

Incentive Structures and Risk Distribution

As a matter of general principle, production costs should be internalised. This is the "polluter pays principle" whereby polluters are forced to account for the external social costs they generate when making private production and consumption decisions.

The process of "internalising" costs which otherwise would fall on third parties is a necessary precondition if market mechanisms are to lead to socially efficient outcomes. Unless firms face the full 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.

Included in the costs which must be internalised are contingent liabilities – risks that future costs will flow from activities undertaken today. There are two main reasons for internalising such costs: to provide incentives to take effective preventive measures; and to ensure that innocent victims are actually compensated when a contingency becomes an actual event. In the case of genetic modification, the main category of external costs to be internalised are potential future damages, contingent on inherently unpredictable future events, and suffered by third parties who are often not in any contractual relationship with the originator of the GMO.

An extensive literature 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 the basis of the current regulatory regime. 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.

Strict liability is increasingly the standard internationally for serious environmental risks. In the US, most courts have held that the Comprehensive Environmental Response, Compensation, and Liability Act imposes strict liability for toxic wastes cleanup and restitution costs. It has been used by the courts to "prevent individuals from hiding behind the corporate shield" and a wide range of firms associated with the principal party have been made liable if that party has insufficient funds to meet cleanup costs.

The European Commission White Paper on Environmental Liability is equally adamant that strict liability be the European standard for "dangerous activities" and explicitly includes GMOs in its scope of coverage. Only "non-dangerous" activities are proposed to be covered by "fault-based" liability.

Liability should not be capped. A cap simply shifts the balance of any damages claim to the government or other parties suffering loss, while reducing incentives on GMO developers to exercise due care. The US nuclear power industry provides a clear demonstration of the outcomes that tend to result when an industry is absolved of full financial responsibility. US legislation that caps owner liability and exempts from liability the designers and manufacturers of nuclear power stations has led to reduced investment in safety design.

An important issue under strict liability is the extent to which it should be possible for GMO developers to transfer their risks to others by means of liability insurance. The main drawback of allowing liability insurance is that it dilutes the incentive on the liable party to minimise the risk of adverse outcomes. The main argument in favour of insurance is that it ensures victims of actually receiving compensation, whereas strict liability on its own could lead to situations in which the liable firm proves to have inadequate financial resources to meet the claim.

Full insurance coverage is not optimal, as GMO developers ought to bear a significant share of their own risks. However, allowing genetic modification firms to go forward uninsured would leave potential victims unprotected in the event that the liable firm goes bankrupt. Insurance thus constitutes the best available deep pocket to prevent actual realised costs from simply lying where they fall – or ultimately being picked up by taxpayers.

Rather than insurance premiums equating to "a penalty on a particular activity or product", as the Commission sees it, insurance represents an opportunity to shed risk and quantify costs that are already present. Only by arguing that risks should be socialised, not internalised, could premiums be described as a "penalty".

Insurance

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 private insurance cover, under a regime of strict liability, be made a condition for securing ERMA consent for either experimentation or release of GMOs. This compulsory insurance would be in addition to a requirement to post a performance bond, such that the insurance would cover claims over and above the bond.

The simplest form of performance bond requires the potentially-liable party to deposit a specified sum for the period during which the risk is expected to remain real, with all or part of that sum being forfeited in the event of a successful claim. In effect, performance bonds would represent a compulsory excess on the firm's liability insurance.

The presence of an insurer behind each GM application is a necessary condition to ensure that third parties receive compensation, and it is a valuable source of ongoing private-sector monitoring and supervision effort once the ERMA approval process has been completed.

The Commission has correctly observed that if there is a requirement to hold insurance, any inability to attract insurance cover will effectively stall an application. However, it then advances the argument that if cover is not perceived to be generally available, there should not be compulsory insurance as "effectively the activity would be prohibited, contrary to the Commission's wish to maintain options". Its rejection of the traditional means of coping with business risk without explicitly proposing who will instead bear that risk leaves a large gap in the analysis, not a solution.

Further, the subject matter is too complex to generalise across all levels of an industry. There will undoubtedly be GMO risks for which insurers will be willing to provide cover today. There will be other classes of risk for which local insurers will require backing from new reinsurance instruments. A further class of risk will be judged too risky for insurers to support on present knowledge. Unless there are compelling reasons to think that ERMA or the Government has an information advantage over the private market, uninsurable risks ought not to be authorised.

If an applicant believes there is a strong national interest in developing a particular uninsurable GMO, 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. Only if the state could subsequently be persuaded to assist would Government actually be the party socialising the losses. Without strict liability and compulsory insurance, innocent (or uninvolved) individuals and businesses would tend to carry contingent liabilities from GMO research unless and until the state chooses to come to their rescue.

As the European Commission White Paper suggests, the best path forward in respect of riskier GMO projects is through continued development of financial instruments that can take the place of conventional insurance. GMOs are categorised as one of a number of Major Technological Risks (MTRs). Like other MTRs, the technology carries the potential for catastrophic levels of damages and in this respect, it has many characteristics in common with natural catastrophes.

The traditional insurance market is prone to fail on both the demand and the supply side, in the face of catastrophic risk. As an alternative, a new class of financial derivatives emerged following major natural disaster claims in the mid 1990s, instruments 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 opportunity existed. Billions of dollars in reinsurance capacity has been created using such capital market instruments.

Allocating Liability

In order to assist in identifying liable parties, especially where more than one party works with the same GMO, a change is required in the ERMA approval process. Rather than ERMA simply deciding on the question of whether a GMO can be released on a once and for all basis, ERMA should consider whether each particular applicant should be granted a release permit. If the approved applicant is ultimately liable for claims arising directly from a particular GMO and proposed programme, it will only make arrangements to use and distribute its commercial product under conditions that take account of its ultimate liability.

The Government has clear financial incentives to protect against any adverse effects resulting from the release of GMOs. At present, it is not only the insurer of last resort where a cleanup response is required and no other party can be compelled to meet the costs, it is also a direct stakeholder due to its responsibility for the nation's biodiversity. Unless the Crown has in place a robust regime that ensures liable parties

are able to meet damages claims, then at least those risks which could result in damage to the nation's biodiversity become Crown contingent liabilities under section 10 (3) (b) of the Fiscal Responsibility Act.

Liability Law Reform in Other Jurisdictions

The EU is currently actively engaged in setting policy in respect of deliberate release of GMOs, making for a moving feast. Specific liability for GMO use at present takes a penal approach. Under the latest 2001 Directive of the EU (Directive 2001/18/EC) addressing GMOs and their release, member states are required to enact "penalties" that will be effective, proportionate and dissuasive. In February 2000 the European Commission separately proposed strict liability for all "hazardous" environmental risks, including GMOs. While the European Commission wishes to commence GMO approvals after a hiatus, we understand that six member states want traceability and liability issues resolved before any further approvals are given.

The present United Kingdom approach is set by the Environmental Protection Act 1990 and in the associated Genetically Modified Organisms (Deliberate Release) Regulations 1992. This imposes duties on GMO developers to monitor potential damage to the environment and focuses on fines for violating conditions, rather than setting liability conditions. It is still too early to determine how the EU Member States will respond to the 2001 Directive on GMOs. However, a British consultation paper on implementation of the Directive refers to existing penalties as potentially being satisfactory but the Blair Government has repeatedly indicated its intention to revisit the question of liability.

The United States does not have a comprehensive regulatory scheme addressing the question of liability for GMO use. Instead, regulation is spread between various federal agencies. Claimants in the United States must rely wholly on the common law doctrines of trespass, negligence, strict liability or nuisance for a remedy. As yet, there are no clearly decided cases establishing common law liability for GMO use.

In Australia, the Gene Technology Act 2000 is the principal statute. Liability for property damage or economic loss is not dealt with specifically under this act. While the Gene Technology Act is intended to regulate all dealings with GMOs across Australia, a national regulatory regime requires states and territories to first enact corresponding laws before the Commonwealth regime is fully operative.

The Current Liability Framework

HSNO is the principal statute governing GMOs. Rather than a strategic approach to regulating GMOs, HSNO provides for the assessment of applications on a case by case basis. The creation of adverse environmental effects is not itself an offence under HSNO. It is breaches of control that are. The emphasis is very much on front-end risk assessment rather than on responsibility for any harm to persons or property.

Liability can arise under section 17(1) of the Resource Management Act (RMA). This imposes a duty to "avoid, remedy or mitigate any adverse effect on the environment arising from an activity carried on by or on behalf of that person." Any person has a duty under this section to "avoid, remedy or mitigate" any potential or real adverse effects on the environment that arise or could arise as a result of release.

However, the main avenues available for redress at present are common law actions. With respect to property damage, this is likely to be by way of the rule in *Rylands v Fletcher* or a nuisance action as these are strict liability offences, and therefore they are easier to establish than a claim of negligence.

The tort of nuisance is committed where a defendant uses his or her land to carry out an activity which causes something foreseeably harmful or offensive to affect the land of a neighbour, to an objectively substantial degree. If the activity causes actual damage to neighbouring land, then there is no defence. However, it is subject to a "foreseeability of harm" test that will exclude liability in cases where an activity thought to be harmless turns out to involve unforeseen risks of harm.

The rule in *Rylands v Fletcher* is a subset of nuisance for cases involving an "isolated escape", where a defendant is making a non-natural use of land. The rule is that persons who keep on their land anything likely to do mischief if it escapes, keeps it at their peril andis answerable for all the damage which arises as a consequence of its escape. Again, it is subject to the foreseeability test.

If personal injury is not caused by an accident or medical misadventure, is not an occupational disease and is not covered under some other head under the Accident Insurance Act (AIA), then a private action for damages is possible. The main possibilities that would not receive cover under the AIA, and thus could be pursued under the common law, are personal injury caused by ingestion not amounting to an accident, or by viruses.

Deficiencies in the Present Regime

The main deficiencies with relying upon the torts actions and the rule in *Rylands v Fletcher* are :

(a) Each tort is dependent on claimants commencing and persevering with a suit. The costs and evidential difficulties in demonstrating causation are substantial and are likely to deter complainants.

(b) GMOs raise issues ill-suited for the tort of nuisance and the rule in *Rylands v Fletcher* to manage in a fashion that promotes substantive fairness to complainants or to defendants – again largely due to problems in demonstrating causation.

(c) Specific liability provisions in statute or regulatory regimes would assist the reinsurance industry in assessing risk of liability for damage. Common law actions are not as quantifiable (unless there is a developed and readily interpreted history).

The practical difficulties with relying upon the forms of action under tort law or the rule in *Rylands v Fletcher* is that neither has been noticeably effective to date in reducing environmental pollution. Often, both the victims of any damage caused through GMOs as well as the persons allegedly responsible for the damage can be numerous, difficult to identify and insubstantial, and the medical, aesthetic, and other harms of pollution are notoriously difficult to quantify.

Such factors potentially lead to daunting forms of litigation involving difficult feasibility assessments for lawyers and plaintiffs as to the adequacy of the remedy, issues of causation and whether the costliness of the litigation is indeed worthwhile. A further problem is that the damage may not become apparent for a considerable period of time, while an action must brought within six years from the date it occurred under the Limitations Act.

However, the design of liability provisions has to be managed sensitively with a view to ensuring that in seeking to ensure claimants have a clear path to recover damages, that this does not result in undue deterrence of investment in GMO research within New Zealand. Thus, liability (whether strict or otherwise) has to also be tied to the fault or blameworthiness of the defendant.

Proposed New Liability Framework

We recommend the following key features in respect of property damage for the new liability framework:

(a) *Transparency and Precision* - Specific liability provisions addressing damage to property consequent upon the release of GMOs assists legal certainty regarding liability and transparency.

(b) *Strict liability* - The strict liability principle in respect of property damage should be: Anyone who sells or uses any genetically modified organism is subject to liability for physical harm, damage or economic loss to property caused by that organism. This principle extends to pure economic loss, including where an organic farmer loses accreditation with an industry representative body.

(c) *Positive duty to Monitor* – There should be an ongoing duty on the applicant to monitor GMO behaviour in field tests, containment, or once released.

(d) *Insurance* - Insurance cover should be a mandatory requirement of any GMO related approval given by ERMA. A performance bond should also be a requirement.

(e) *Mitigation of Liability* - Circumstances might occur where it would be inequitable to have the injurer paying full compensation for the damage caused. Some attention must be given to the reasonable reliance that

might be placed upon a GMO user's compliance with the conditions imposed upon his or her application for release.

(f) *Defences* – An absolute defence to liability would be *force majeure*, in the sense of natural disasters.

Rather than attempt to modify the existing tests in the accident compensation legislation to deal with GMO accidents, it seems preferable to deal with all personal injury claims under the accident compensation legislation. Otherwise some events that result from GMO may fall within the terms of the legislation and others outside. If this policy is adopted, it will be necessary to create under the accident compensation legislation a Genetically Modified Organisms Account. It will also be necessary to provide the capacity to levy those who hold consents or approvals for the release of GMOs in New Zealand.

Reforming Legislation

The key reform requirement is amendment of the HSNO Act so as to:

- Impose strict liability for the supply and use of GMOs
- Set out defences that mitigate strict liability
- Establish joint and concurrent liability
- Make liability insurance a condition of ERMA approval
- Require applicants to post a performance bond
- Provide for ERMA to issue applicant-specific permits for each use of a GMO
- Require permit holders to continually monitor and report to ERMA