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

1. The New Frontiers

1. The Royal Commission on Genetic Modification (the Commission)[1] has labelled biotechnology "the new frontier". It heralds biotechnology as another step along the path of progress comparing it to developments such as fire, the wheel, electricity, space travel and nuclear power.[2]

2. Along with the potential benefits the Commission sees 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). These risks include threats to the environment and human health deriving from effects that are unexpected and irreversible.

3. 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"[3] - it was all the more important that the Commission provide a thorough review on this question.

4. Its work in respect of liability issues however is not a thorough review. The Commission has not put forward the required analysis to support its recommendation that there be no change to the existing liability regime.

5. This report critiques the Commission's work in respect of liability issues and then commences afresh the investigation of what changes might be required to the existing legal framework to produce one that would properly meet the challenges posed by any future release of GMOs. This 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. This too is in its early stages of development and changing rapidly in an attempt to keep up with a fast moving science characterised by strong interdependencies.

6. 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

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1 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.

2 Commission Report, p. 3.

3 Ibid.

- 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 contract out of or protect their positions.

7. In simple terms, a liability regime must pre-define:
   - **Who is responsible**: In broad terms, the three parties that may be called on to meet liability claims are:
     - The parties responsible for the action causing harm;
     - The Government - as a means of meeting a collective liability on behalf of all citizens;
     - The people and businesses who individually actually suffer the harm.
   - **For which actions:** Which activities or types of risk are covered and which are excluded?
   - **Under what conditions:** In what circumstances does liability arise and when is a party not liable?
   - **Over what time period:** How long a period can separate the action and a claim for damages being filed?

8. This report presents the baseline research needed to assess the adequacy of the current liability regime with respect to the release of GMOs into the environment, the requirements for change, and the form this new regulation should take. It has been prepared by Chen Palmer & Partners and Simon Terry Associates Ltd on a *pro bono publico* basis.[4]

Definitions

If release of a GMO results in significant harm, it will tend to cause financial losses. When these losses are framed as a legal claim, they are known as damages.

The laws and regulations that govern who is responsible for meeting damages claims are collectively termed the liability regime.

[4] Reproduction costs of this report were assisted through sponsorship from Bio-Gro and we gratefully acknowledge this assistance.

2. The Commission's Position

9. This section reviews the Commission's position in respect of liability issues. Readers familiar with its findings should proceed directly to our core critique set out in section 2.4.

2.1. The Commission's Task and Current Applicable Law

10. Key sections of the Commission's warrant that require it to investigate liability issues include the following:

> (e) the liability issues involved, or likely to be involved, now or in the future, in relation to the use in New Zealand of genetic modification, genetically modified organisms, and products."
>
> (c) the risks of, and benefits to be derived from, the use or avoidance of genetic modification, genetically modified organisms, and products in New Zealand, including –
> (i) the groups of persons who are likely to be advantaged by each of those benefits; and
> (ii) the groups of persons who are likely to be disadvantaged by each of those risks.[5]

11. A separate chapter is devoted to the reporting of liability issues (Chapter 12). Following a general introduction, the Commission begins by setting out its interpretation of the existing liability framework. We discuss this in detail in Section 7 so the following simply notes the Commission's key conclusions on the principal laws making up that framework..

Hazardous Substances and New Organisms Act 1996 (HSNO):

- Strict liability if ERMA conditions for experimentation are broken.
- Essentially no liability in respect of damage that occurs once release has been authorised by ERMA.

Resource Management Act 1991 (RMA):

- Remedies "may be available" but are restricted to effects on the environment.[6]

Civil or Common Law

- If a claim is not barred due to coverage by the Accident Insurance Act 1998, "the claimant can bring a damages claim based on negligence".[7]
- "Nuisance is a tort protecting the use of land, so claimants can sue only if they have an interest in land. The defendant's liability is based upon possession and control of the land from which the nuisance emerges".[8]

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5 Commission Report, p. 365
6 Commission Report, p. 314
7 Ibid, p. 314
8 Ibid, p. 318

- The Rylands *v* Fletcher rule "has been regarded as an extension of the law of nuisance" and "the rule applies to the 'escape' from the defendant's land of something likely to cause damage". "… the defendant must be in possession or control of the land from which the "harm" came and be making a "non-natural" use of the land; and the possibility of escape and the consequent harm must have been foreseeable, although the manner or immediate cause of the escape need not have been foreseeable." [9]

Accident Insurance Act (AIA) 1998

- Damage caused by ingestion or exposure to genetically modified organisms or genetically modified products over time would not be covered under the scheme, but a common law action would be possible.
- It is "possible" that the AIA covers medical misadventure – "personal injury caused by medical error or medical mishap" - and also "personal injury caused by a work-related gradual process, disease or infection" may be covered.[10]

2.2. Approach to the Investigation

12. The Commission notes early in Chapter 12 that "An overriding concern [of those submitting] was whether it was appropriate to leave liability to be decided according to the current regulatory and legal frameworks."[11] In the course of its reporting, the Commission noted the following concerns which are relevant to the adequacy of the current regulatory regime.

> There was particular concern about who would bear the responsibility for environmental damage, such as adverse effects on biodiversity if invasiveness turned out be a characteristic of genetically modified plants.[12]
>
> The effects of genetic modification are expected to:
> • be likely to manifest only in the long term
> • be diffuse in nature
> • involve difficulties and expense in establishing proof of cause, nature and extent of any damage.[13]
>
> Whether liability was to be assumed by the state as a "socialisation of the risks" of genetic modification; or whether the producer or user should be responsible for any damage under a "polluter pays" approach.[14]
>
> A number of submitters raised the prospect of the loss of valuable markets or even the wholesale collapse of the organic farming sector, with no clear avenues of redress, in the event of general release of genetically modified crops.[15]

9 Ibid, p. 318
10 Ibid, p. 316
11 Ibid, p. 311.
12 Ibid, p. 311.
13 Ibid, p. 311.
14 Ibid, p. 312.
15 Ibid, p. 312.

> The damage done by modified organisms, some submitters suggested, could be cumulative rather than acute. … environmental harm could result from an accumulation of ecologically insignificant instances of horizontal gene transfers in the soil biosphere.[16]
>
> The issue concerning submitters was not the speed with which such damage would be caused, but that it would be irreversible.[17]

13. Thus, the Commission clearly recognised concerns with respect to how the existing liability framework would cope with GMO related claims. At this point, we would expect a focus on these and other such challenges to test the robustness of the current regime. Failure of the current framework to handle a reasonably forseeable event would suggest a need for reform.

14. However, the Commission did not adopt such an approach. Instead, it proceeds directly to focus attention on proposals from submitters. In both the introduction and the conclusion to Chapter 12, the Commission listed the following issues (here taken from the conclusion), implicitly framing its list of issues for investigation.

> Proposals included:
> • the imposition of strict liability, meaning that third parties sustaining injury or damage could recover damages if they could prove a causative link with the genetically modified product, without having to establish conventional legal elements such as negligence or nuisance
> • the establishment of some fund providing compensation for persons sustaining injury or damage
> • those using or selling genetic modification technology or products should be required to enter into a bond for the benefit of persons sustaining injury or damage.[18]

15. These are undoubtedly key potential reforms. However, the absence of an analytical framework within which to consider them is a crucial failing, as is further discussed below.

16. The following sets out the Commission's responses to the three proposals above. Our full analysis of the Commission's positions is set out in the following sections but we briefly comments here on the points raised.

Strict Liability:

The Commission's complete statements on the issue of strict liability are as follows:

> Strict liability can be a barrier to innovation and progress, and the weight of international precedent is against setting up such a regime: the United States, Canada, the United Kingdom and Japan do not impose strict

16 Ibid, p.55.
17 Ibid, p.55.
18 Ibid, p. 327.

> liability and instead rely on the common law or general environment protection legislation for those seeking recourse. Significantly, the first three countries all have a legal background largely similar to our own. On the information before us, the only major countries with a strict liability regime are Germany and Austria.[19]
>
> The effect of the [Rylands v Fletcher] rule is to impose a higher standard of responsibility for activities with inherent risks. Since, however, such activities generally have utility for the community, they should not be subjected to the kind of disincentive a rule of absolute liability would impose.[20]

Comment:

- Regulation in respect of GMOs is still under development but a clear trend in those countries engaging with the issue is towards strict liability.
- The Commission is implicitly proposing that for "activities with inherent risks", at least some of these risks should be transferred to other parties.

Dedicated Compensation Funds:

The Commission offers no explicit position on this concept. The following is the best indication of its stance:

> In theory, Superfund is supposed to enforce a "polluter pays" policy. That is, if culpable parties can be linked to a polluted site, they must pay for cleanup efforts. In practice, Superfund's rule of "retroactive, joint and several and strict liability" has been claimed to result in lengthy and expensive litigation, delays and inefficiency in clean ups, waste and even fraud; …[21]

Performance Bonds:

The Commission's discussion on insurance and bonds is a little fuller than that on the previous two mechanisms. It notes the potential role of bonds in providing against: undercapitalised, insolvent or departed companies and those that fail to comply with regulations.[22] It describes the instrument as follows:

> Commonly, the person who has to give the bond provides a performance bond, underwritten by an insurance company. Such bonds are obtainable from insurers operating in New Zealand. The bond guarantees the performance of the person who is required to fulfil the statutory requirements, … . Failure to comply will trigger forfeiture of the bond.[23]

19 Ibid p. 328.
20 Ibid, p. 318.
21 Ibid, p. 324.
22 Ibid, pp. 319, 323.
23 Ibid, pp. 323, 324.

However, it cites two grounds for rejecting this mechanism.[24]

> The substantial premiums involved would equate to a penalty on a particular activity or product, disadvantaging those wishing to trade in the field, compared with other industries.
>
> At the present time, having regard to the difficulty in assessing the risk because of limited knowledge and experience about genetic modification, and the unlikelihood that reinsurance could be obtained, it is improbable that insurers would take on such risks.

Comment:

- Insurance premiums are a standard cost of business. Removal of this cost is an implicit subsidy, not a penalty.
- If insurers will not take on certain risks, this reduces the chances of claimants successfully obtaining damages payments, thus increasing the chances that the risks are simply transferred to unprotected third parties.

17. The Commission does not provide sufficient justification for the rejection of the first and third proposals, and does not directly address the second. Further, the Commission makes no substantial references to literature outside that presented to it by submitters. While it commissioned independent research on how the existing regime would be likely to respond under claims for damages, it does not appear to have similarly researched reform options. The discussion provided is simply inadequate as a substitute for analysis. It provides no clear basis for assessing whether a particular mechanism will actually cover any perceived gap in the existing regulatory regime.

2.3. The Commission's Recommendation

18. The Commission's answer to the central question – is change required – is given in the following paragraph.

> The Commission considers it is unnecessary to recommend legislation providing special remedies for third parties, where they may have been affected by the release of a genetically modified organism. As technology advanced with ever-increasing pace throughout the 20th century, the common law (that is, law based on court decisions, as distinct from statute law) showed it was well able to mould new remedies for novel situations. Parliamentary intervention has rarely been needed in this area. From a legal liability perspective we have not been persuaded there is anything so radically different in genetic modification as to require new or special remedies.[25]

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24 Ibid, p. 323.

25 Ibid, p. 328.

19. As the concluding rationale for the Commission's recommendation, "that for the time being, there be no change in the liability system"[26], this is unsatisfactory. The Commission has not presented the analysis required to demonstrate that GMOs do not represent one of those "rare" instances where specific statutory reform is required. The Commission instead presents its opinion that no change is required. Its thinking is in effect collapsed into, and is dependant on, its statement that "we have not been persuaded there is anything so radically different in genetic modification".

20. We do not believe the Commission's discussion on its own provides an informed basis for government to determine whether a sound liability regime is in place.

2.4. Socialisation of Risk

21. 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 … [27]

22. The Commission had earlier implicitly acknowledged that damages claims resulting from the release of GMOs would be more difficult than the norm to sustain for a number of reasons.

> "The effects of genetic modification are expected to:
> • be likely to manifest only in the long term
> • be diffuse in nature
> • involve difficulties and expense in establishing proof of cause, nature and extent of any damage."[28]

23. Thus it is difficult to square this reported greater difficulty of obtaining compensation with the Commission's view that "From a legal liability perspective we have not been persuaded there is anything so radically different in genetic modification as to require new or special remedies."

24. The degree of socialisation of risk will in effect be dependant on:[29]

- The willingness and financial capacity of affected parties to initiate and persist with an action;
- How difficult it proves to be to "establish that the defendant's activity or product caused the damage" ; and
- The ability of the claimant to obtain payment: "The defendant may be a shell company without substantial assets, or may be insolvent."

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26 Ibid, p. 329.
27 Ibid, p. 328.
28 Ibid, p. 311.
29 Ibid, pp. 318,319

25. As the Commission observes, the more unforeseen and unanticipated the loss, the more it will be socialised.

26. The Commission can consistently argue that, to the extent it sees nothing "radically different" in respect of GMOs, then the degree of socialisation should not be appreciably different to that resulting from other activities. However, given the Commission's wide brief and its rejection of strict liability, an important flaw in the Commissions work is its failure to provide any discussion on the prospect of the Crown taking explicit responsibility for at least those losses arising from unforeseen and unanticipated circumstances.

27. While the Commission may well opt for "some socialisation" of losses, it is also incumbent upon it to then consider where those losses are actually likely to fall within society and the options for influencing that distribution of risk.

28. New Zealand has a history of socialising a class of losses arising from personal injury so there is a clear precedent for this model. And the Commission notes the existence of the US Superfund – an industry and federally funded body intended to meet the emergency costs of cleaning up chemical wastes if the polluter could not be made to.

29. In absence of any recommendation for such a Crown or industry funded body, the starting position for socialisation is that losses will fall on innocent parties (often third parties) and will remain with them until they can persuade the government that it should assist.

30. Thus responsibility for the contingent liabilities associated with unforeseen and unanticipated losses rests heavily with individual citizens and businesses. They individually carry damages if something goes wrong unless and until they can prove someone else should be responsible, or government decides to step in.

31. This issue of allocation of risk is crucial to the design of a liability regime and is the central question we pursue, especially in Sections 4, 5,8 and 9.

3. Potential Damages

32. This section examines the nature, scope and form of potential damages that could conceivably arise from the release of GMOs into the environment. The analysis does not predict any particular occurrence, it simply seeks to describe the forms of damages claims that could arise. Readers familiar with the nature of the risks and damages should turn to section 4.

3.1 Classes of Risk

33. GMOs tend to be regulated under environmental law and they have effectively been classed as a new set of environmental risks. Framing an appropriate liability regime will be assisted by understanding the relative level of risk posed by GMOs.

34. Environmental regulation was initially framed around rather visible sources of pollution that were ultimately biodegradeable. These included: sewage, wastes from animal processing, oils, grease, and acids. The regulations focused on the assimilative capacity of the environment to set site specific discharge limits. This first phase of pollution control in the 1970s centred on the rate of discharge and resulted in significant improvements in water quality in particular.

35. However, a number of technologies produce substances which are not readily broken down and assimilated into the natural environment. Rate of discharge regulation is quite unsuited for these but new modes of regulation have been quite slow to develop. Even the recognition that there were new types of risks that are fundamentally different in character has come slowly.

36. The clearest early example was radioactive material at the point nuclear power was being commercialised in the late 1950s, and early 1960s. It was already clear from the atmospheric nuclear explosions that fission residues represented a quite different form of risk to biological systems. Though it was not described in the following terms at the time, we now recognise its characteristics to include the following:[30]

    - Bioaccumulative
    - Persistent
    - Irreversible
    - Highly toxic in very small quantities

37. More recently, a significant number of industrial chemicals have been found to have similar properties. In particular, synthetic chemicals containing chlorine

[30] *Key Lessons from the Long History of Science and Technology: Knowns and Unknowns, Breakthroughs and Cautions*, Parliamentary Commissioner for the Environment, March 2001, p. 13.

(known as organochlorines) have slowly been identified as a particular and separate class of risk.

> Organochlroines account for the majority of known endocrine disrupters; a large portion of identified carcinogens; a great number of chemicals that damage the nervous, endocrine, reproductive and immune systems, and virtually all the world's persistent organic pollutants.[31]

38. With growing recognition of such new risks, by 1987, Germany was able to persuade representatives at the Second International Conference on the Protection of the North Sea to adopt the precautionary principle as part of international law for the first time. The conference agreed that the discharges of substances that are "persistent, toxic and liable to bioaccumulate" should be prevented at source, "even where these is no scientific evidence to prove a causal link between emissions and effect".[32]

39. As the Commission notes, New Zealand has adopted the precautionary principle in a number of international agreements including the 1992 United Nations Conference on Environment and Development (the Rio Declaration) and the United Nations Cartagena Protocol on Biosafety.

40. Article 11.8 of the Biosafety Protocol, is directly relevant and it states:

> Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of that living modified organism intended for direct use as food or feed, or for processing, in order to avoid or minimise such potential adverse effects.

41. In an important respect, the precautionary principle has already found its way into the key legislation relating to the potential release of GMOs, the HSNO Act. Clause 25 states that:

> (1) No –
> (a) Hazardous substance shall be imported, or manufactured:
> (b) New organism shall be imported, developed, field tested, or released –
> Otherwise than in accordance with the approval issued under this Act or in accordance with Parts XI to XVI of this Act.

42. Taken together with Clause 3 of the 1999 amendment to the Act (which specifies that one definition of a new organism is "a genetically modified organism"), the Act clearly establishes two things.

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31 *Pandora's Poison: Chlorine, Health and a New Environmental Strategy*, Joe Thornton, MIT Press, 2000, p. 15. See also *Our Stolen Future*, Theo Colborn, Dianne Dumanoski, and John Peterson Myers, Penguin Books, 1996.

32 Ibid, p 344 and *Reinterpreting the Precautionary Principle*, Tim O'Riordan, James Cameron and Andrew Jordan, Cameron May, 2001, p. 11.

- The first is that, in line with the precautionary principle, all GMOs are presumed hazardous until proven otherwise. The burden of proof is placed on the applicant to at least show that the risks of research or release are ones it can convince ERMA are not unreasonable.

- The second is that, by itself, the classification of all GMOs under the HSNO Act calls into question the Commission's view that there is nothing especially different about GMOs from a liability perspective. The Act governs only substances recognised to be hazardous or which are new organisms where new organisms as a class have shown the potential to be hazardous. By definition under the Act, GMOs are considered to pose higher risks. It is indeed the case that the authority administering the Act, the Environmental Risk Management Authority (ERMA), is tasked with filtering out the GMOs it judges to be most risky. However, this is not the Commission's claim and even if it was, this filtering simply mitigates the frequency of unforeseen harm: it does not alter the scale of potential damage this class of risk is capable of generating.

43. The Ministry for the Environment's extensive submission to the Commission documented the long gestation of the HSNO Act and the numerous practical instances of damage resulting from the introduction of new organisms through importation which led to new organisms in general being viewed as a special category of risk.

> There were recent examples of new organism releases which had the potential for damaging consequences, and which pointed to deficiencies in the current controls on new organism imports. Examples which prompted such concerns were the introduction of chinchilla, Channel catfish brought in quarantine as part of an economic development scheme with Maori interests and then destroyed, and marron crayfish for which commercial breeding operations were established and then permission withdrawn requiring the destruction of the stock and a substantial compensation payment.[33]

44. The lead taken by New Zealand in establishing through the HSNO Act this special set of procedures for new organisms (including GMOs) is now being matched by jurisdictions such as those under the European Commission. The EU White Paper on Environmental Liability similarly seeks to bring under shared law within the European community regulations governing dangerous substances, hazardous waste, and GMOs.[34] An important difference however is that the White Paper also moves on to propose parallel reform of the liability regimes in member countries. This is further discussed in section 5.1.

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33 Ministry for the Environment submission to the Commission, p. 18.

34 White Paper on Environmental Liability, European Commission, February 2000, p. 17.

45. The concept of classes of risk is further recognised within the HSNO Act through provision for ERMA to classify hazards by "prescribing for each intrinsic hazardous substance property a number of degrees or types of hazard."[35]

46. 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.

47. This self-perpetuation is not confined to simple reproduction of the original form. One of the acknowledged risks is mutation and/or gene transfer. Thus, GMOs pose a level of potential clean up cost that is not readily subject to pre-estimation.

48. Dr David Suzuki, a geneticist by training and a leading international ecologist, summed up this picture in his witness brief to the 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.[36]

3.2 Scope of Damages

3.2.1 Damages Categories

49. 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**
  Including adverse reactions to the consumption of foods and medicines containing GMOs.

- **Damage to Biodiversity**
  Including effects on existing species by GMOs that result in reductions in numbers of particular species (on a localised or national basis) or species extinction.

- **Economic Loss**
  Including property damage or economic loss resulting from GMO contamination of land, crops, processed foods and other products

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35 Clause 45. While the classification system is framed only for substances, not new organisms, it is the principle of the legislation providing for different classes of risk that we note.

36 Commission Report, p. 55.

50. These categories are consistent with the scope of damages proposed to be covered by law common across the European Union relating specifically to environmental risks.[37]

51. The Commission was informed of other potential sources of harm that could result from the release of GMOs including submissions from Maori in respect of "spiritual pollution" and those from a range of parties in respect of New Zealand's "clean green" image.[38] A Ministry for the Environment study "suggests this [clean green] image is worth at least hundreds of millions, possibly billions of dollars" and that one of the exposures to loss is perceptions about the extent to which GMOs are present in the New Zealand environment.[39] However, only to the extent that these types of harm relate to the categories above can they be captured under damages claims at present.

3.2.2 Pathways to Damage

52. Before examining particular types of damage claims that could arise under these categories, it is useful to distinguish four different pathways to damage.[40] This analysis by pathway focuses on how the inserted gene(s) could travel, or behave, in unexpected ways to illustrate the general nature of the risks in question.

1. **Displacement:** Any mechanism by which the GMO spreads beyond a designated area. The GMO grows as intended but outside the place intended. This includes the following displacement mechanisms:
   – wind, bees, lab wastes or other carriers transferring GMOs to another place – also known as "genetic drift";
   – accidental release from laboratories, unauthorised deliberate release, unintended release from laboratories.

2. **Unintended Effects.** Observed effects that were not intended in the design of the GMO but are resulting attributes. These unintended affects may or may not have been detected or hypothesised during testing and approval phases. These include:
   - effects on other organisms (soil bacteria, insects, animals and plants);
   - effects on humans from consumption of the GMO.

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37 The European Commission covers the same scope in three differently labeled categories which are: site contamination, damage to biodiversity and traditional damage (the latter including personal and property damage and economic loss). As well as damage resulting from GMOs, it covers damage from hazardous waste, hazardous substances, and biotechnology in general. *White Paper on Environmental Liability*, European Commission, February 2000, pp. 17, 18.

38 Commission report, pp. 57, 95.

39 *Valuing New Zealand's Clean Green Image*, Ministry for the Environment, August 2001, preface.

40 A further less serious category is sometimes cited as the additional chemical burden placed on the environment by GM varieties that explicitly require greater use of chemical additives to be made.

3. **Mutation:** Acts within a species. The original genetic structure is altered through breeding with natural plants or animals of the same species to produce a new strain. (This is sometimes known as vertical gene transfer.)

4. **Gene Migration:** The inserted gene migrates to other species. This is formally known as horizontal gene transfer.

53. The above pathways are consistent with a number of different categorisations for the purpose of risk assessment and the Commission accepted each as a relevant risk.[41] .

54. With respect to the first of displacement, the Commission clearly accepted the pathway as valid and its focus was simply on the degree of risk posed and the potential for buffer zones and physical barriers to mitigate damage.[42] Similarly, the Commission gave a number of examples of unintended side effects, the second pathway.[43]

55. With respect to the third pathway of mutation, the Commission again accepted the principle but pointed to different degrees of risk, commenting that:

> The risk of the escape of a transgene through vertical gene flow is different for plants and animals. … It would seem to be easier to contain the outcrossing of transgenic animals than transgenic fish or plants.[44]

56. With respect to the fourth pathway of horizontal gene transfer, the Commission noted that this "appears to be common between microorganisms, such as bacteria and fungi". It further stated with respect to plants that the Commission was supplied with "scientific references to show that there are many routes available for such transfer to occur".[45]

57. A report by a Committee of the US National Academy of Sciences is noteworthy on the issue of gene transfer. The Committee on Genetically Modified Pest-Protected Plants concluded that:

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41 *The Journal of Molecular Ecology* (vol 3, 1994) listed the following categories as environmental risks of genetically engineered crops:
1. Invasiveness of the transgenic crop (in the agricultural system as a weed or in natural habitats)
2. Invasiveness of transgene itself (vertical gene flow through hybridisation with wild relatives)
3. Side effects of the transgenic products (for instance effects on non-target organisms).
Source: Royal Commission Report, p 51, quoting Professor Klaus Ammann, Director of the Botanical Garden, University of Bern, Switzerland, appearing for the New Zealand Life Sciences Network.

42 Commission Report, pp. 174-177.

43 Commission Report, pp. 58, 43, 60-61.

44 Ibid, pp. 51,52.

45 Ibid, pp. 49, 50

> On the basis of the literature, the committee found that pollen dispersal can lead to gene flow [the transfer of genetic information from one organism to another] among cultivated crops and from cultivated crops to wild relatives.[46]

3.3 Types and Sources of Damage

3.3.1 Introduction

58. This section examines the types of damage that could attract legal liability as a result of the release of GMOs. It focuses on the deliberate release of GMOs into the environment, either for research purposes or for marketing. This type of release would include, for instance, the planting of GMO seeds for crop or seed production. It could also include the importation from other jurisdictions of agricultural commodities, such as maize or soya, for direct use as food or animal feed, or for processing into food products such as refined oils.

59. The sources of damage identified below are not exhaustive and derive, in part, from the identification of the aspects of an activity, substance or organism that may cause harmful effects to humans or to the environment already recognised as "hazards".[47] The likelihood of hazards being realised and the magnitude of the effects or consequences are conventionally termed "risks". "Hazards" can cause damage and it is the identification of such hazards together with the quantification (where possible) of "risk" that can cause legally actionable damage. While actions seeking damages have already been launched in other jurisdictions, there is not a sufficient body of settlements to date to provide good guidance to the level of damages that GMO release could entail.

60. However, the European Union and its member states provide useful guidance for New Zealand on the nature of the "risks" and potential responses to these as a number of the EU member states have taken a close interest in the issue, as has New Zealand.
61. Of interest is that under the EU regime established by Directive 90/220/EC the member states since 1998 proved unable to attain agreement on the approval of any new GMO products under Part C of that Directive (that is, commercial releases).

> Part of the reason for this impasse is concern about the longer term environmental effects of the management of commercial cultivation of certain GM crops, particularly those expressing herbicide tolerance. The concern is focussed not on the GM crop itself but on the possibility that

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46 National research Council, *Genetically Modified Pest-Protected Plants: Science and Regulation*, National Academy of Sciences, 2000, pp. 9,10.

47 For instance refer to *Guidance for Environmental Risk Assessment and Management* (United Kingdom, Department of the Environment Transport and the Regions (DETR) 2000). Cf. the potential sources of damage that Professor Stephen Todd identified in his paper "Liability issues involved, or liability to be involved or in the future, in relation to the use, in New Zealand, of genetically modified organisms and products," www.gmcommission.govt.nz.

> GM herbicide tolerant crops could exacerbate wildlife declines if they encouraged higher levels of weed control than necessary, which in turn could reduce invertebrate and bird numbers.[48]

62. Since 1990 the European Commission has only issued fourteen approvals placing GMOs on the market. In contrast, the United States, Japan, and Canada, have permitted "general release" for nearly one hundred genetically modified products.[49] In June 1999 the EU member states agreed to implement a de facto ban on future approval of GMO consents pending the implementation of the new EU framework under Directive 2001/18/EC. That is, as with New Zealand, an effective moratorium has been in operation.

63. At the time of writing, environmental liability is subject to much contention and fluidity within the EU. We understand that the European Commission wishes to commence GMO approvals again but that six member states, led by France, are resisting, and have announced a preference for the liability issues to be resolved before any further run of approvals occurs. On the information we have received, France wants traceability issues regarding GMOs refined and detailed before GMO approval processes begin in earnest. As a result of such difficulties, we understand that the EU is looking at bringing forward a draft EC Directive on GMO liability issues towards the end of 2001.[50]

3.3.2 Personal Injuries from Allergenicity or Toxicity

64. One possible source of damage involves personal injury. Allergenicity and toxicity are possible causes of injury in this context. The potential allergenicity of GM crops is an issue of concern for regulatory agencies in the United Kingdom and is one class of personal injury that might arise from genetically modified plants. Relevant scientific evidence indicates that a diverse range of plants induce IgE mediated hypersensitivity in humans, which may result in various clinical syndromes such as asthma, conjunctivitis, rhinitis, and, on rare occasions, anaphylaxis.[51]

65. Although asthma and anaphylaxis tend to constitute the rarest allergic conditions (the incidence of asthma in New Zealand is relatively high), they can be

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48 Department for Environment, Food and Rural Affairs (DEFRA), United Kingdom, *A Consultation Paper on the Implementation of Directive 2001/18/EC on the Deliberate Release into the Environment of Genetically Modified Organisms* (July 2001), p. 10.

49 P Clarke, "Europe takes hard line on genetically modified crop approvals", *Farmer's Weekly*, 11 December 1998, p. 58; A Bryan Endres, "GMO: Genetically Modified Organism or Gigantic Monetary Obligation? The Liability Schemes for GMO Damage in the United States and the European Union", 22 *Loy L A Int'l & Comp L Rev* 453, 469-470 (2000).

50 The forerunner of such draft has been circulated for comment to select parties.

51 IgE is immunoglobulin E. IgE hypersensitivity is where an antigen (e.g. from a bee sting) enter the body. If the antigen has entered the body before, immunoglobulins (antibodies) have been formed specific to that and wait in the body in case they ever see that particular antigen again in order to launch an immediate response. The specific IgE antibody binds to that antigen and then both bind to other cells and the binding releases substances that promote an immediate response – usually allergic.

potentially fatal. It is acknowledged that allergens from plants, including GM plant matter, can intrude into the body through pollen inhalation, the ingestion of food, flesh contact with a growing crop or the food. The question arises, therefore, as to how a company developing GM crops can appraise the potential allergenicity of a new genetic modification.

66. The paradigm of the toxic hazard is the occupational or environmental carcinogen. Toxicity poses specific evidential difficulties for courts and the legal profession as it involves questions of statistical and epidemiological evidence hedged with a modicum of uncertainty in the underlying reasoning. GMO hazards, in this context, are those occupational or environmental toxins characterised by several qualities. First, persons are exposed to them in a chronic fashion often typified by relatively low dosages of exposure. Second, the persons so exposed often lack awareness of the toxic effect during the initial phase of the exposure. Third, the exposure can be followed by a period of latency before the injury or disease manifests itself in the person. Fourth, the hazardous property does not remain in the afflicted person's body in a manner that clearly links the disease or injury with the hazard. Four methods are resorted to in identifying carcinogenic hazards:

    - Cluster analysis;
    - Short-term molecular assays;
    - Animal bioassays; and
    - Epidemiological studies.[52]

67. Suffice it to say that methods such as epidemiological studies are imbued with probabilistic notions of causation. Epidemiological analysis increases the statistical confidence that a certain exposure, for instance, to asbestos, will have caused an increase in the risk of lung cancer. This stance is accomplished through eliminating the effect of other variables, including smoking, diet or increased age. Accordingly, epidemiology selects some condition from a list of several and seeks to demonstrate that it is associated with a certain form of damage in a fashion that could be presented statistically. The modern concept of causation is premised on probability considerations not on reductionist causal links between individual actors.[53]

68. Hence, toxicity is a useful illustration not only insofar as it requires attention to be had to the problems of proving causation in personal injury – but also in that it demonstrates the problems of causation that haunt the risks associated with GMO hazards generally. Indeed, the problems of causation bedevilling claims of toxicity should also be borne in mind when considering each of the following possible sources of damage.

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52 For a useful discussion of "toxicity", *vide*, Brennan, "Causal Chains and Statistical Links: The Role of Scientific Uncertainty in Hazardous-substance Litigation", 73 *Cor L Rev* 469 (1988).

53 See Swiss Reinsurance Company, *Genetic Engineering and Liability Insurance: The power of public perception* (Zurich, 1998), p. 9.

3.3.3 Effects on Non-target Species

69. 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 significant food resources (such as invertebrates) which the organisms may depend upon for survival. A Cornell University study has found that pollen from corn genetically modified to produce the toxin Bacillus thuringienis (Bt) is fatal to monarch butterflies for instance.[54]

70. The negative outcome in question is often characterised as a secondary or non-target adverse effect.[55] Under this heading, relevant points to address include:

    (d) Which species feed on, or otherwise come into contact with, the GMO or transgenic plant;

    (e) Whether the pollen of the transgenic plant contains the new gene product and, if so, what the potential effects may be on the non-target organisms such as bees, aquatic organisms, since plant pollen has the potential to enter into adjacent environments through wind dispersal;

    (f) Whether the GMO is expressed in seed or fruit and, if so, whether animals consume these products;

    (g) Whether the GMO is sufficiently stable to digestion such that the species feeding on the transgenic plant would accumulate enough of the novel genetic material to affect predatory species consuming them.

71. Within the EU, Austria and Luxembourg have introduced measures prohibiting or restricting the use of Bt maize crops.[56] This has posed some political difficulties for the EU under Directive 90/220/EC indicative of the debates that can arise as to the potential risks of GMOs. Under Article 15 of 90/220/EC, where a product containing a GMO or a combination of GMOs is placed on the market and has been duly authorised pursuant to the Directive, an EU member state may not, on grounds relating to matters covered in the Directive, restrict or impede the deliberate release of the product on its territory (provided that the GMOs comply with the requirements of the Directive). Austria and Luxembourg have relied upon Article 16(1) of Directive 90/220/EC which provides:[57]

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54 John E Losey et al, "Transgenic Pollen Harms Monarch Larvae", *Nature*, 20 May 1999, at 214, referred to in Endres, "GMO: Genetically Modified Organism or Gigantic Monetary Obligation? The Liability Schemes for GMO Damage in the United States and the European Union", 22 *Loy L A Int'l & Comp L Rev* 453, 454 (2000).

55 OECD, *Report of the Working Group on Harmonisation of Regulatory Oversight in Biotechnology* (Paris, 25 May 2000), 14.

56 Endres, "GMO: Genetically Modified Organism or Gigantic Monetary Obligation? The Liability Schemes for GMO Damage in the United States and the European Union", 22 *Loy L A Int'l & Comp L Rev* 453, 474 (2000). K J Kuilwijk and C Pouncey, "Genetically Modified Organisms: Proposed Changes to the EU Regulatory Regime", (1999) 5 *International Trade Law & Regulation* 89, 90.

57 The Commission refrained from taking these member states to court even though Luxembourg and Austria have maintained bans and the Commission approved the product.

> Where a Member State has justifiable reasons to consider that a product which has been properly notified and has received written consent under this Directive constitutes a risk to human health or the environment, it may provisionally restrict or prohibit the use and/or sale of that product on its territory. It shall immediately inform the Commission and the other Member States of such action and give reasons for its decision.

3.3.4 Invasiveness in the Environment

72. The dispersal of the GM crop in the environment through the possibilities of increased persistence, intrusiveness and competitiveness with existing native or exotic plant species which could subtly (and eventually perhaps significantly) alter the population dynamics and ecological balance of the release site and surrounding environment. To illustrate, if New Zealand native plant species suffer severe competition with an invasive plant and decline, there would also be reductions in the animal species which directly and indirectly depend on them for survival. This is of relevance to the management of the conservation estate, as well as to farming and forestry.

3.3.5 Contamination and Gene Transfer

73. Transfer of genetically modified material to other crops through pollination by wind or insects is one of the more usually appreciated possible adverse effects. Hence, for instance, the inheritance of pest resistant genes in closely related exotic or native plant species could confer a significant selective advantage over other plant species, because feeding by insects or birds remains an important factor in controlling population growth in plants. As a result, these accidentally hybrid native plants could become more competitive and, again, potentially invasive in terms of their surrounding environment. Moreover, cross-pollination can result in genetically modified material contaminating organic crops.

74. The quantum of economic damage in this area has already been demonstrated.[58] In 1998 the corn of a certified organic farmer in Texas was contaminated through cross-pollination from a neighbouring field of GM corn. This contamination was not noted until the corn was processed and exported to Europe as organic tortilla chips. DNA testing revealed traces of GM corn and the entire export shipment (valued at US$0.5 million) was rejected and destroyed. Apparently, the tortilla chip manufacturer determined not to pursue the organic farmer for damages but joined Greenpeace and the Center for Food Safety as plaintiffs in a lawsuit filed against the United States Environmental Protection Agency (EPA) in February 1999. A $10 million claim against Monsanto is pending in Canada.[59]

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58 The following account is extracted from Richard Repp, "Biotech Pollution: Assessing Liability for Genetically Modified Crop Production and Genetic Drift", 36 *Idaho L Rev* 585, 591 (2000).

59 *Ibid*, 592.

3.3.6 Rare Events

75. Perhaps the most difficult possibility of damage that might prompt novel legal liability questions is that of the "rare event", an incident that introduces consequences, or effects, of a disastrous magnitude in circumstances where the risk of occurrence was uncertain or not readily quantifiable. Often a "rare event" can be an exogenous shock in the sense of it arising or occurring through unforeseen circumstances and mediated *via* external agency or agencies (an intruding epidemic for instance – influenza following the 1914-1918 war; bubonic plague in the mid-fourteenth century and at subsequent intervals, as with London in 1665; foot and mouth disease in Britain in 2001). These "rare events" can be marked temporally by either relative persistence (as with the escape of radioactive material from a nuclear plant) or an ephemeral quality (a passing, singular incident that nonetheless generates much damage).

76. An illustration of a relatively persistent episode is the epidemic incidence of bovine spongiform encephalopathy (BSE) in the United Kingdom. It is noteworthy that the calamitous quality of this episode was not accompanied by any ease in determining the causes or origins of BSE. A review committee assessing the origins of BSE and required to report to Ministers issued its findings on 5 July 2001 and concluded that epidemic incidence of BSE arose through the use of meat and bone meal (MBM) in cattlefeed.[60] Costs can be egregious. In respect of the parallel case of foot and mouth disease, this had cost the United Kingdom more than £1 billion in compensatory payouts by 13 August 2001.[61]

77. In the area of genetic modification, the potential for such "rare events" directly raises questions of causation and associated evidential problems, as well as the degree of reasonable foreseeability and fault or blameworthiness that can be imputed to the human source of the GMOs.

78. Conceptually, the occurrence of a "rare event" need not be the outcome of a hitherto absent GMO (a purely exogenous invasion or intrusion) but could be a "delayed effect" or a "cumulative long-term effect". Clearly, either of these forms of effect might relate as much to the preceding classes of source of damage as to a "rare event" category. Instructively, Directive 2001/18/EC of the European Parliament and Council (dated 12 March 2001) defines the phrase "cumulative long-term effect" under Annex II ("Principles for the Environmental Risk Assessment") as referring to:

> [T]he accumulated effects of consents on human health and the environment, including inter alia flora and fauna, soil fertility, soil degradation of organic material, the feed/food chain, biological diversity, animal health and resistance problems in relation to antibiotics.[62]

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60 Ministerial Review Committee, *Review of the Origin of BSE* (5 July 2001). The *Report* notes that the EU Scientific Steering Committee has not yet released its own findings.

61 A Browne, "Thousands face ruin as farmers prosper", *Guardian Unlimited*, 12 August 2001, www.guardian.co.uk.

62 This Directive repealed the Council Directive 90/220/EEC. The case law under Council Directive 90/220/EC generally concerns the alleged failure of EU member states to meet their

79. The term "delayed effects" is defined under Annex II of the European Parliament and Council Directive 2001/18/EC as follows:

> "Delayed effects" refers to effects on human health or the environment which may not be observed during the period of the release of the GMO, but become apparent as a direct or indirect effect either at a later stage or after termination of the release.

80. Managing the possible long term, indirect, delayed or cumulative effects on wildlife and the environment through releasing and using GMOs such as crop plants is understood to represent an underlying objective to the new EU Framework to be established under Directive 2001/18/EC.[63]

3.3.7 Novel Scientific Developments

81. Finally, an additional area of concern should be recognised. Novel applications of biotechnology are under development and there are emerging possibilities that established concepts such as *familiarity* might be challenged. *Familiarity* as a concept operates relatively well insofar as it can be used to address the environmental risks associated with GMOs. The concept of familiarity is based upon the notion that most genetically engineered organisms to date are developed from organisms such as crop plants whose biological properties are well appreciated. Such a concept facilitates risk appraisal; it is not a risk assessment itself. It permits a regulatory agency to draw upon previous awareness and historical experience with the introduction of plant types into the environment and can suggest appropriate forms of risk management.[64]

82. Yet, novel technologies might begin to unhinge the reliability of the concept of familiarity or any confidence in it. Many GMOs will begin to carry "stacked" or multiple genes. Also, novel combinations of genes from diverse organisms might generate an impact that is not readily quantifiable or appreciable.

83. An example is the controversial Genetic Use Restriction Technology (GURT), also known as "terminator technology" or "sterility technology". This genetically modifies the source plant so that it produces only sterile seeds. The attraction for seed producers is that it forces farmers to purchase seeds afresh for each growing

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obligations of enacting legal mechanisms to comply with the Directive: e.g. *Commission of the European Communities v Grand Duchy of Luxembourg* (1996) ECR I-5143 (Case C-312/95); *Commission of the European Communities v Kingdom of Belgium* (1998) ECR I-4291 (Case C-343/97). The *Report of the Royal Commission on Genetic Modification – Report and Recommendations*, I, pp. 325-326 does not refer to the 2001 Directive except insofar as to claim that the European Parliament had not approved the Directive. Yet, the Directive 2001/18/EC entered into force on 17 April 2001 and it takes effect from October 2002.

63 DEFRA, *A Consultation Paper on the Implementation of Directive 2001/18/EC on the Deliberate Release into the Environment of Genetically Modified Organisms* (United Kingdom, July 2001), p. 9.

64 OECD, *Safety Considerations for Biotechnology: Scale-up of Crop Plants* (Paris, 1993).

cycle. The chief concern associated with this technology is that if horizontal gene flow occurs, and the genes responsible for sterility migrate to other species, it could have devastating impacts.

84. While many international agricultural research institutes have banned research into this technology, more than 30 patents are held in respect of it. In August 2001, the US Department of Agriculture officially sanctioned commercialisation of a GURT technology by licensing it to a major seed company, Delta & Pine Land, which has stated that it intends to commercialise GURT seeds.[65] The Commission itself expressed interest in the technology and stated that "The Commission considers the use of sterility technology in commercial forestry trees should be investigated, as it has the potential to reduce pollen production with its associated allergenicity problems and prevent wild pine escape."[66]

[65] *USDA Says Yes to Terminator*, Rural Advancement Foundation International, August 2001, p. 1 and Commission report, p. 178.

[66] Commission report, p. 178.

4. Incentive Structures and Risk Distribution

85. This section begins our examination of the principles that should guide design of a sound liability regime. It opens discussion on the issues of risk distribution and how to set incentive structures through reference to the concept of internalising costs. Later sections then examine implementation mechanisms, existing New Zealand law, and recommended reforms.

4.1. Internalising Costs

86. A general principle in the economics literature is that, wherever possible, economic agents should both be able to appropriate at the margin the economic value which they create, and face the full marginal costs of their activities. Both value-added and costs are measured in terms of the economy-wide (i.e. "social") impact of the activities concerned. In perfectly-functioning markets, the effects which expansion or contraction of a firm's activities have on the wider economy and society are signalled by the prices which it receives for its outputs and pays for its inputs. In the real world there are important components of human welfare for which markets do not exist, with the result that some consequences of the activities of firms remain external to the revenues and expenditure streams faced by firms' managers, and hence external to their profit-maximising calculus and decision-making process.

87. There are a range of productive activities which impose on third parties the prospect of uncompensated losses because of lack of enforceable property rights and/or absence or inefficiency of relevant markets or regulation. Simple examples are loss of amenity values from the siting of highways, operation of airports, smoking in restaurants, industrial air or water pollution. The common feature of these cases is that the costs borne by third parties are external to the primary agent. The victims are not in any contractual relationship with the "polluter", and hence have not had the opportunity to embody any compensation element into the prices which it faces.

88. The appropriate policy response to protect the actual or prospective victims of negative externalities depends on the circumstances, but will fall somewhere along a spectrum of measures ranging from command-and-control regulation at one end across to the creation of property rights and quasi-market pricing mechanisms at the other. In the ideal case, regulatory intervention can be limited to altering the prices faced by polluters and then leaving them to respond to the resulting incentive to mitigate their damaging activities.

89. This in essence is the origin of the "polluter pays principle". As Lewis[67] notes,

[67] Lewis, T., "Protecting the Environment when Costs and Benefits are Privately Known", *Rand Journal of Economics* 27(4):819-847, Winter 1996, pp. 843-844.

> Environmental economists have exposed policy makers to the virtues of the 'polluter pays' principle whereby polluters are forced to account for the external social costs they generate when making personal production and consumption decisions…. Incentive regulation relies on self-interested privately informed individuals to select their best option for reducing pollution.

90. 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. 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.

91. The primary alternative to the polluter pays principle is the socialisation of risk. As ERMA pointed out in its submission to the Royal Commission:[68]

> Philosophically, there are two approaches that can be taken to the issue of liability in this regard. The first is to argue that by creating the HSNO framework ie requiring those wishing to develop, test or release GMOs to obtain a formal approval, the State is effectively relieving those people of liability for unexpected results. The nation as a whole takes the risk. The previous Minister for the Environment, Hon Simon Upton, has referred to this as the "socialisation of risk". The second approach is to argue that the intervention of the State through the regulatory process notwithstanding, those wishing to develop, test or use GMOs are most likely to gain any immediate benefits from that, and also can reasonably be expected to have good knowledge (perhaps better than the regulator) of the risks. It is therefore not unreasonable that the operator should retain some liability.

92. The accident compensation scheme is an example of the full socialisation of risk and liability. Here, the individuals covered for personal injury have clear incentives to avoid that injury. The party to be compensated is inseparable from the party responsible for exercising care. However, this is not the case with commercial technology development. The party undertaking the development can separate itself quite considerably. The greater the separation, the more the proper economic incentives are compromised. Hence, full socialisation of the risks by government was not cited by the Commission as having been put forward by any submitter.

93. A number of factors dictate the extent to which costs are in fact internalised by firms. Relevant institutional variables are the nature and extent of private property rights, the extent to which government uses its powers to tax and subsidise as a means of changing the prices and costs which firms face in the markets where they trade, and the legal framework within which both private parties and the

[68] ERMA submission, p. 32.

public collectively (through the state) enforce the property rights allocated to them.

94. Not all negative externalities occur contemporaneously with the activity which causes them. There are a range of productive activities which have imposed on third parties the prospect of uncompensated future losses in the event of "accidents". Familiar industrial examples are processes which produced toxic by-products that are persistent and which can affect third parties now and in the future – possibly the quite distant future. These substances, the effects of which were not well anticipated at the time of manufacture and/or use, include: dioxin, PCBs, certain tanalising compounds, DDT , and the use of asbestos in buildings. In these cases the external costs of the activity will only occur with some (often unknown) probability, will affect third parties whose identity is not known in advance, and have a magnitude which is known only with hindsight. The costs which must be internalised to achieve economic efficiency are therefore contingent liabilities – risks that future costs will flow from activities undertaken today.

95. There are two central reasons for internalising such costs: to provide incentives for today's actors to take effective preventive measures to minimise the risk of future accidents; and to ensure that innocent victims are actually compensated for their losses when a contingency becomes an actual event.

96. In the case of genetic modification, the main category of external costs to be internalised are of this kind: 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. Both the likelihood of occurrence of damage, and its magnitude, are largely unknown at the time the release of a new organism is undertaken.

97. Insofar as any party possesses superior inside information on either the probability or the magnitude of damage, that party is likely to be the firm developing and marketing a particular GMO. Consequently, in selecting an institutional mechanism to minimise the prospect of damage from genetic modification, attempts by policymakers and regulators unilaterally to implement economic instruments such as taxes or tradeable permits are likely to be inferior to arrangements which confront individual firms with costs based on their own informed expectation of potential damage.

4.2. Mechanisms for Internalising Costs

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

4.2.1. Strict Liability

99. 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 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.

100. An extensive economic literature[69] 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.

101. 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,[70]

> 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...

102. Strict legal liability appears to be the key (albeit not perfect) means by which external costs arising from GM activities can be internalised.[71] A discussion of

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69 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.

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

71 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;

the nature of the recommended strict liability test to be applied is contained in section 9.2.

4.2.2. Capped Liability

103. Similar problems to applying simply the negligence standard would arise if the state capped the liability of GM firms, thereby either assuming itself, or loading onto victims, the residual risks.

104. The European Commission White Paper cautions against capping liability: "Capping liability for natural resource damages is likely to improve the chances of early development of the insurance market in this field, [but] would erode the effective application of the 'polluter pays' principle".[72]

105. The nuclear power industry provides a highly relevant demonstration of the outcomes that tend to result when an industry is absolved of full financial responsibility for its actions. The parallel between nuclear power and GMO development is that both carry the risk that very large damages claims can result from a single release incident. Radioactive material and GMOs are classed as special categories of environmental risk.

106. When nuclear power was being commercialised during the late 1950s and early 1960s in the United States, it was championed as the new frontier of its day amidst over-optimistic claims about its potential (for example the statement that "It is not too much to expect that our children will enjoy in their homes electrical energy too cheap to meter"[73]).

107. While there may have been boundless optimism in respect of running costs, the financial risks were nevertheless judged so severe that in 1957 the United States Congress passed the Price-Anderson Act which currently caps the liability of the civilian nuclear power industry at less than US$10 billion. Each utility owner must carry just $200 million in liability insurance per reactor, and contribute up to an additional $84 million in the event of an accident. The Price-Anderson Act also exempts from liability the designers, manufacturers and component suppliers to nuclear power stations.[74]

> With the financial risks to the industry effectively reduced, there was less incentive to adopt a precautionary approach to the technology. Consequently, many studies and experiments into the safety of nuclear reactors that had begun in the 1950s were not completed before commercial reactors started being built in large numbers. The basic safety flaws of the 1950s designs had been identified within a decade, but the

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72 *White Paper on Environmental Liability*, European Commission, February 2000, p. 23.

73 Lewis Strauss, Chairman, US Atomic energy Commission, 1954.

74 *"A Renaissance That May Not Come"*, The Economist, May 16 2001, and www.taxpayer.net.

> designs were used anyway because of the heavy investment that had been made in them.[75]

108. Investigations that followed the Three Mile Island accident did not just criticise the operation of the plant. They also found the manufacturer of the plant (Babcock and Wilcox) at fault. However, as noted, under the Price-Anderson Act the firm was exempt from liability.[76]

109. The ongoing relaxation of incentives that the capped liability represents doubtless raised the risks of further serious nuclear accident in the United States. In 1986, the then Commissioner of the Unites States Nuclear Regulatory Commission stated that:

> Given the present level of safety being achieved by the operating nuclear power plants in this country, we can expect to see a core meltdown accident within the next 20 years, and it is possible that such an accident could result in offsite releases of radiation which are as large as, or larger than, the releases estimated to have occurred at Chernobyl.[77]

110. Reactor safety has improved in recent years, particularly since the deregulation of the US wholesale electricity market in 1996 and the commercial pressures on utilities that accompanied this. However, the Price-Anderson Act, originally intended to provide 10 years of "temporary" assistance, has been renewed four times and Vice President Dick Cheney has stated that "It needs to be renewed...[again as if not], nobody's going to invest in nuclear-power plants."[78]

4.2.3. Insurance

111. An important issue under strict liability for GMO developers is the extent to which it should be possible for their risks to be transferred 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 take sufficient care to minimise the risk of accidents. The advantage of strict liability over a negligence standard was that it forces the firm to bear its own risks. The essence of liability insurance is that the risks are transferred to another party, which in a sense returns the firm to a position similar to that under a negligence standard – facing only the financial consequences of its own negligence if any, plus a known (non-risky) insurance premium.

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75 *Key Lessons from the Long History of Science and Technology: Knowns and Unknowns, Breakthroughs and Cautions*, Parliamentary Commissioner for the Environment, March 2001, p. 13.

76 *Price-Anderson Act Special Subsidies And Protections For The Nuclear Industry*, Jill Lancelot, Taxpayers for Common Sense, July 2001, p. 3.

77 *The Nuclear Power Deception: US Nuclear Mythology from Electricity "Too Cheap to Meter" to "Inherently Safe" Reactors*, A Makhijani and S Saleska, 1999.

78 *"A Renaissance That May Not Come"*, The Economist, May 16 2001

112. 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, once faced with a serious damages claim, proves to have inadequate financial resources to meet the claim in full.

113. The theoretical conditions under which liability insurance should be allowed with no restrictions have been explored by Shavell.[79] He points out that if firms are risk-averse, strict liability without insurance could theoretically lead to excessive effort being devoted to preventive care, whereas a risk-neutral insurer would design its insurance terms and conditions to secure an optimal level of care. This, however, depends on the insurer being both fully informed about the risks, and able to monitor the firm's actions effectively. Where monitoring ability is limited the problem of moral hazard arises (that is, the firm, having disposed of its risk exposure, can act without due care without attracting any sanction from its insurer; the insurer, assuming it is aware of this, will increase its premiums accordingly).

> [W]hether risk averse injurers will purchase full cover depends on whether liability insurers can 'observe' the levels of prevention activity of individual injurers. If liability insurers cannot do this, then, clearly, they cannot link the premium or terms of the policy to the level of prevention activity. Consequently, were injurers to purchase complete coverage, there would be a problem of moral hazard: Injurers would have no reason to avoid accidents, would therefore be involved in accidents with high probability, and would find themselves paying a high premium per dollar of coverage. But if injurers purchased policies with incomplete coverage, they would be exposed to some risk, and would therefore have some inducement to avoid accidents, would be involved in accidents with a lower probability than before, and would therefore pay a lower premium per dollar of coverage (though still an actuarially fair premium – given their altered behaviour). Hence, it would seem plausible and can be shown under quite general assumptions that injurers would in fact purchase policies with incomplete coverage.
>
> On the other hand, if liability insurers can observe prevention activity, then they can make the premium or other policy terms depend on such activity, thereby giving injurers an incentive to avoid accidents even if they purchase full coverage.
>
> …
> … In the case when injurers are risk neutral and liability insurers cannot observe prevention activity, injurers would decide against purchase of liability insurance. The reason is that because of moral hazard, the cost of insurance coverage would exceed an injurer's expected cost were he not to purchase coverage; and since protection against risk is of no consequence to him, he would not buy coverage.[80]

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79 Shavell, Steven, "On Liability and Insurance", *Bell Journal of Economics* 13(1):120-132, Spring 1982.

80 Shavell, Steven, "On Liability and Insurance", *Bell Journal of Economics* 13(1):120-132, Spring 1982, p.127.

114. Shavell's framework points strongly to the optimality of incomplete, but not absent, insurance coverage for most GM activities. All parties, including potential insurers, are incompletely informed about the actual risks of adverse consequences from the development and/or release of new organisms. Probabilities of disaster are low and may not be calculable. Outcomes of an actual disaster are ambiguous *ex ante*[81] and expectations about those outcomes, therefore, will take the form of ranges rather than point estimates, and will be characterised by ambiguity. Monitoring of prevention activity is necessarily imperfect, partly for the usual reasons of asymmetric information between firms and their insurers, and partly because the nature and extent of optimal prevention itself cannot be specified in the absence of full information about outcomes.

115. All of these points suggest that full coverage is not optimal and that GMO developers ought to bear a significant share of their own risks – both to enable insurers to bring premiums down, and to avert moral hazard.

116. On the other hand, allowing GM firms to go forward uninsured would leave potential victims unprotected in the event that catastrophe happens and the liable firm goes bankrupt. Insurance then constitutes the best available deep pocket to prevent actual realised costs from simply lying where they fall – or being picked up after the event by taxpayers.

4.3. Collective Insurance and Contingent Liability Accounting

117. If insurance is a necessary mechanism, one question is whether the coverage should be individually obtained or held collectively?

118. The theoretical advantage of any collective cover is that in bundling together all GM firms, the risks carried attendant to each single firm are diluted by the other firms. In theory, such aggregation could make cover more attractive to offer and/or reduce premiums.

119. However, the New Zealand market for GM insurance will be very small in relation to the level at which there would be meaningful gains to insurers from

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81 Frisch, Daniel D. and Baron, Jonathan, "Ambiguity and Rationality", *Journal of Behavioural Decision Making* 49, 1988; Kunreuther, Howard and Hogarth, Robin M., "Risk, Ambiguity and Insurance", *Journal of Risk and Uncertainty* 5, 1989; Ritov, Ilana and Baron, Jonathan, "Reluctance to Vaccinate: Omission Bias and Ambiguity", Chapter 6 in Sunstein, Cass R. (ed) *Behavioral Law and Economics*, Cambridge University Press, 2000. Ambiguity is a familiar problem in corporate decision-making on the technological frontier; "Most strategic steps are taken in an atmosphere of extremely high ambiguity, especially in the early stages. A new product or manufacturing process is an interesting possibility, but answers to questions of successful manufacture, time frame, cost, market impact, and risk are all highly uncertain. The high-level executive decision to move ahead with such a project is a political act…. [M]ost senior executives … recognize that decisions must be made, even in the face of high ambiguity …" (Langevoort, Donal C., "Organized Illusions: A Behavioral Theory of Why Corporations Mislead Stock Market Investors (and Cause Other Social Harms)), Chapter 5 in Sunstein, Cass R. (ed) *Behavioral Law and Economics*, Cambridge University Press, 2000, p.159.

aggregation. The wider the scope of activities that are brought into the grouping to raise the size of the portfolio, the more it focuses attention on another problem already inherent in the small grouping. That problem is the lack of uniformity of risk profiles.

120. Even looking at only GMO developers, some firms will be undertaking research which is, overall, considerably less risky than that pursued by others. Some will have better safety, auditing, training, or financial backing than others. To the extent one firm can persuade an insurer that it is a better class of risk, it can achieve lower cost cover and it will have a disincentive to share that advantage. Further, to the extent there is any doubt about more risky firms gaining cover at all, the incentives are even stronger to go it alone. These points are accentuated the more consideration is given to expanding a GMO grouping to include biotechnology in general, or all hazardous substances.

121. The most widely known scheme that has some relationship to collective insurance is the Superfund created under the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA). The act establishes a multibillion dollar Superfund to pay for removing wastes and for remedial actions connected with the cleanup. The majority of this is funded by taxes on targeted substances (petroleum and chemical feedstocks) but a significant minority is funded from general taxation. However, rather than a compulsory collective insurance arrangement, the fund is intended only as a means of paying for cleanup costs if no liable party can be identified or meet the claims. It is therefore more like a fidelity fund in its character.[82]

122. The prime focus of the act however is to hold responsible persons and companies liable for toxic wastes cleanup and restitution costs.

> Most courts have held that section 107 imposes strict liability for toxic wastes, not dependent upon fault. … Plus, courts have frequently found joint and several liability exists among responsible generators, transporters, owners and operators, even though section 107 does not specify this.[83]

123. One US court has declared that "CERCLA prevents individuals from hiding behind the corporate shield when, as 'operators,' they . . . actually participate in the wrongful conduct prohibited by the Act." and the U.S. Supreme Court has stated

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82 The Hazardous Substances Trust Fund is known as Superfund. The Superfund Amendments and Reauthorization Act of 1986 (SARA) revised and expanded CERCLA. This 1986 Act increased the fund from its original $1.6 billion budget to $8.5 billion for the 1986-91 cleanup period. Legislators then estimated SARA would raise $2.5 billion *via* a surtax on businesses exceeding $2 million annual incomes; $2.75 billion from a petroleum tax, $1.4 billion from a tax on chemical feedstocks, $1.25 billion from general revenues, $300 million from interest on trust fund money, and $300 million from cleanup costs the government would recover from liable parties. Sources: *CERCLA Overview*, Environmental Protection Agency, and *Confused About CERCLA?*, Lindsey Martin-Bowen, www.paralegals.com/Reporter/Winter96/CERCLA.html

83 *Confused About CERCLA?*, Lindsey Martin-Bowen, www.paralegals.com/Reporter/Winter96/CERCLA.html

that "As its name implies, CERCLA is a comprehensive statute that grants the President broad power to command . . . private parties to clean up hazardous waste sites." [84]

124. The European Commission White Paper is equally adamant that strict liability be the 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.[85]

125. Paralleling the international legal trend towards strict liability for environmental damage are moves to raise accounting disclosure standards with respect to contingent liabilities, including those deriving from environmental risk. In New Zealand, a significant revision of the 1993 disclosure standards applies for financial reporting periods ending on or after 31 October 2001. Two provisions likely to be relevant in respect of GMOs are:[86]

- A contingent liability must be disclosed if (a) a present or possible obligation arises from a past event and (b) the outflow required to settle the obligation is likely to occur, but cannot be measured reliably;

- Entities shall disclose information from which it is possible to identify and evaluate exceptional risks of operating.

126. If strict liability is introduced, then as the exposures represented by GMO development make their way into company accounts, there will immediately be scrutiny as to which of the exposures are offset by insurance arrangements. Bankers, shareholders and brokers who do not see insurance cover in place will make their own judgements about lending risks and adjustments to net tangible assets. Through this mechanism, even non-quantified contingent liabilities will impact on firms.

127. The incentives to secure insurance cover will be all the stronger. 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 Commission sees 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". Any transfer of these costs is in fact an implicit subsidy.

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84 *Riverside Market Development v. Int'l Building Products,* 931 F.2d 330. (5th Cir.) and *Key Tronic Corp. v. United States et al.*, U.S, 114 S.Ct. 1960 (1994).

85 *White Paper on Environmental Liability*, European Commission, February 2000, p18.

86 *FRS-15: Provisions, Contingent Liabilities and Contingent Assets*, Institute of Chartered Accountants, FRS-15: 4.3 and FRS-9: 8.14.

5. Insurance and Compulsory Cover

This section examines the insurance arrangements that should be introduced to properly internalise the risks of GMO research and development. It also proposes changes to the form of approval ERMA would give to successful applicants.

5.1. Performance Bonds and Compulsory Liability Insurance

5.1.1. A Missing Discipline in the HSNO Act

128. At present, ERMA is not empowered to require a bond or any other assurance that an applicant can meet claims for damages resulting from unanticipated effects or a failure to comply with ERMA conditions.

> The Authority's general approach to date has been that provision for public liability insurance cover is at the discretion of the approval holder. As the law stands at present, there is no mechanism for the Authority to include as a control on an approval the requirement to have public liability insurance.[87]

129. However, ERMA itself has stated that "it might be appropriate to go further".

130. Discussion over the original penalty and liability provisions to be contained in the HSNO legislation did note the potential for significant damages claims to arise and even the prospect of liable parties being insolvent. The 1992 discussion paper proposing the HSNO legislation stated that "Recovery of costs for damage caused, or for cleaning up required, needs to have priority over other claims for companies going into receivership as a result of a severe hazardous substances incident."[88]

131. However, official thinking in relation to HSNO was heavily focused on control structures. The philosophy was that as long as the control structures were strong and there were serious penalties for breaching the controls, this would be sufficient protection. This emphasis on disciplining the agents handling the regulated substances was reinforced in the report of the Select Committee considering the HSNO bill in 1995. Its only references to liability were in respect of raising the level of fines to be imposed on individuals due to "the potential for breaches under the bill to lead to greater adverse effects than the more general resource management offences".[89]

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87 ERMA submission to the Commission, p. 31.

88 *Hazardous Substances and New Organisms: Proposals for Law Reform*, MFE, 1992, p. 43.

89 *Hazardous Substances and New Organisms Bill: Report of the Committee on the Bill*, House of Representatives, 1995, p. 10.

132. The problem with such a heavy reliance on control structures is that the regulator must accurately foresee all the circumstances in which something could go wrong and must be able to prescribe for these in advance. GMOs were still in their infancy in the early 1990s.[90] However, one of the biggest sources 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. Some adverse GMO contamination may never be able to be fully cleaned up, but this will not obviate claims for damages.

133. The limitations of the HSNO legislation in this respect are made clear by comparison with current developments in the European Union where the European Commission has proposed that member states adopt strict liability provisions in respect of hazardous waste, dangerous substances, and biotechnology and specifically GMOs.[91] This is to cover traditional damage to property as well as to biodiversity. It stops short of proposing that arrangements for financial security be compulsory and leaves this to member states to individually determine. However, the European Commission makes clear the desirability of compulsory cover to ensure adequate funds are available to meet claims.

134. The following examines how this discipline can be inserted into the HSNO Act.

5.1.2. Objectives and Instruments

135. Two objectives should guide the design of new arrangements to make applicants financially accountable for their projects.

- **To incentivise the firm undertaking the risky activity to take due care**. This requires strongly incentive-compatible arrangements to induce firms to undertake effective preventive and safety measures. This implies strict liability provisions which force those firms to face substantial costs in the event of accident or other unforeseen adverse consequences of release, together with some mechanism which ensures that these firms are not able entirely to transfer liability risk to other parties.

- **To ensure those harmed actually receive compensation.** Liability must be backed by deep pockets to ensure that actual protection and compensation is provided. This means that the applicant must show it has been accepted for cover under sustainable insurance and reinsurance arrangements prior to any approval for experimentation with or release of new organisms, and the cover must remain effective long after actual release.

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90 It is also questionable how effective the risks of hazardous substances can be anticipated, even though more is know about most of them.

91 *White Paper on Environmental Liability*, European Commission, February 2000, p. 17.

136. The two instruments which, in combination, hold out the best prospect of providing for these linked objectives are performance bonds and compulsory liability insurance.

137. Performance bonds are one instrument which already exists in New Zealand environmental law: section 108 (1) of the Resource Management Act (RMA) provides for bonds to be posted to cover environmental risks. It is unclear why the RMA's provision for performance bonds was not carried over into the HSNO Act which was being developed at the same time as the RMA and was originally intended to be a subsection of it.[92]

138. In its submission to the Royal Commission ERMA noted that "using the precedent of the RMA it would be feasible to require operators to post a bond against the costs caused if adverse consequences arise from the improper application of controls".[93] However, on their own, bonds would only represent an adequate solution if reliable estimates could be made of the potential damages and this is not the case. More importantly, ERMA is only proposing this discipline in respect of breaches of controls when there is the potential for large scale damage irrespective of whether controls are obeyed, as ERMA acknowledges.

> "The real issue with GMOs is that of unexpected adverse effects which prove to be inadequately controlled by the containment regime or unforeseen at the time of approving release. This concern comes through from public submissions under HSNO, and arises because the technology is new and powerful and there is uncertainty about its potential to create unexpected adverse effects."[94]

139. Liability for damages over and above the amount of the relevant performance bond or bonds is a matter for insurance. Compulsory private insurance cover for those risks, under a regime of strict liability, should be a necessary condition for securing ERMA consent for either experimentation or release of GMOs.

140. Compulsory insurance both provides the "deep pockets" (without which strict liability offers little real protection) and forces companies to open themselves to a degree of supervision by commercial insurers. These insurers have commercial incentives to identify which firms and projects (i) carry acceptable risks and (ii) merit confidence in the safety measures put in place to protect the public and the environment.

5.1.3. Performance Bonds

141. The simplest form of performance bond requires the potentially-liable party to deposit a specified sum of money for the period during which the risk is expected

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92 The Ministry for the Environment (MFE) did recommend (but did not have accepted) a proposal for ERMA to be able to require bonds for containment research only. Source: MFE submission to the Commission, paragraph 104. .

93 ERMA submission to the Commission, p. 31.

94 Ibid, p. 32.

to remain real, with all or part of the deposited sum being forfeited in the event of accident or other unforeseen damage to the environment and/or third parties. The first rationale for this arrangement is that the liable party suffers a direct financial penalty in the event of damage, and the prospect of such loss provides an incentive to act prudently. Its function is to bring a capped liability to bear directly on the firm to minimise moral hazard, while at the same time providing a test of the financial fitness of the firm involved. At present, the company and its employees are not liable under the HSNO Act so long as their actions are prudent, even if these actions clearly harm third parties.

142. The second rationale is to ensure ready access to at least a sizeable block of funds to actually meet damages claims. These can be difficult to extract for a number of reasons:

> The costs associated with collecting funds from responsible parties through litigation are very high. Many potentially responsible parties declare bankruptcy when it is time to collect cleanup costs, thereby isolating them from their normal responsibility.[95]

143. As the Commission notes, bonds that are required under Acts of Parliament are generally provided by way of a performance bond, underwritten by an insurance company.[96] In these circumstances, the insurance company is incentivised to monitor the financial health and activities of the firm. However, such underwriting gives firms the ability to transfer even their performance-bond risk to insurers has the potential to dilute those firms' incentives to act with due care. To avoid this issue of moral hazard, a superior solution would be to require performance bonds to be underwritten by the bank servicing the ERMA applicant.

144. This proposal draws on a line of precedent developing in the United States where creditors closely associated with a firm that has failed to meet environmental liability claims, and banks in particular, have been held accountable for damages.

> In the case of *US vs Fleet Factors Corporation* in 1990-91, the bank was found liable for clean-up costs on the basis that its participation on the financial management of the firm gave it 'an ability to influence' the overall management of the firm even if the bank was not directly involved in the operations. … The court stressed that it wished … to encourage lenders to monitor and supervise more closely their borrowers' environmental policies and practices while basing lending decisions upon sound environmental processes.[97]

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95 Tietenberg, Tom, *Environmental and Natural Resource Economics*, HarperCollins 1996, p. 482.

96 Commission report, pp. 322, 323.

97 Boyer, Marcel, and B. Sinclair-Desgagné, "Corporate Governance in the Presence of Major Technological Risks, Chapter 11 in Folmer, H. et al (eds), *Frontiers of Environmental Economics*, Edward Elgar 2001, pp. 275-276.

145. In effect, performance bonds would represent a compulsory excess on the firm's liability insurance. Liability for damage over and above the amount of the relevant performance bond would then be a matter for insurance.

146. Two considerations should guide the setting of the scale of the bond:
- The scale of potential damages; and
- The objective of incentivising safety-oriented performance.

147. As both considerations would need to be satisfied, and one may involve a lesser sum than the other, the higher of the two estimates should be the guideline. At a minimum, the performance bond should at least equal the excess on the insurance cover so that the insurance can become operational at no cost to other parties.

148. Bond levels should however be subject to a review on application after say three to five years. Firms that could demonstrate through work undertaken during that period that the GMO in question represents a lower level of risk than first thought could have their bond requirements reduced.

5.1.4. Compulsory Liability Insurance and its Availability

149. 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.

150. The Commission has correctly observed that if there is a requirement to hold insurance as a condition for ERMA approval, 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, then there should not be compulsory insurance as "effectively the activity would be prohibited, contrary to the Commission's wish to maintain options".[98]

151. This line of thinking is a poor approach to problem solving. Rejection of the traditional means of coping with business risk without explicitly proposing who will instead bear that risk just 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 as the Commission has. The picture will be quite different at different levels.

152. There will undoubtedly be GMO risks for which insurers will be willing to provide cover today. These will tend to be for applications that are perceived to entail low level exposures.

[98] Commission report, p. 323.

153. There will be other classes of risk for which local insurers will require backing from new reinsurance instruments. Here the barrier (if any) to insurability is the time required for development and widespread adoption of those new financial instruments. (We discuss this in detail in the following subsection)

154. 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, such uninsurable risks ought not to be authorised.

155. Responses from the insurance and financial markets to firm's requests for liability insurance will provide information of value to policymakers and regulators. In effect, these markets are performing an independent vetting of the applicant and the technology. While traditional insurance markets are known to be prone to failure in the face of low-probability high-ambiguity risks (see section 5.2.1 below), recent advances in the global reinsurance industry have arguably done more to remedy that particular market failure than any government or regulator could do. Buttressed by reinsurers with the ability to lay off risks through new insurance-linked securities, the local insurance market ought to be able to provide the necessary barometer of levels of risk accompanying GMO research and release.

156. Containment research in the laboratory poses, for example, minimal risk of large claims for damages, and thus would be expected to be more readily available and at lower cost than cover for release of the same GMO. If faced with these relative costs, the researcher will tend to carefully examine just how much additional information is really gained through a field trial or open release as opposed to simply augmenting containment research. The incentives for such consideration are at present very weak and are arguably biasing the timing of release into the environment.

157. An important function of insurers will be to identify different classes of risk and accompanying requirements that may be placed on GM firms as a condition of obtaining cover. It appears that ERMA already thinks in terms of classes of risk when undertaking its assessment procedures. It told the Commission that "… there is merit in grouping GMO types and or types of applications on the basis of common risk characteristics. A position can be then taken on the acceptability or otherwise of these generic risks."[99] Thus it is a natural extension both for ERMA to consider performance bond levels by class of risk, and for private insurers to undertake similar rating exercises.

158. It is beyond the scope of this study to provide even preliminary descriptions of GM risk categories. That is a substantial and separate research task. However, an important issue to be addressed in establishing the process for setting the bond level is how to reduce the opportunities for applicants to game the regulator.

[99] ERMA submission to the Commission, p. 2.

159. The aim of any applicant will be to have its application classified in the lowest possible risk category, as this will reduce the cost of performance bonds and insurance cover. In order to protect against gaming behaviour, explicit guidelines will need to be set by ERMA for its performance bond assessments. These may make reference to international classification systems and also provide for independent review to be called for, either by the applicant or by potentially affected parties. The willingness of private insurers to cover an application will also constitute a check on the adequacy of ERMA's classification procedures.

160. If the insurance and/or reinsurance (financial) markets are unwilling to support a particular application on the basis of present knowledge, this may be telling ERMA something important. The problem may be one of the markets simply being slower to understand the risks, in which case the solution will come with time and improved knowledge. The barrier posed by an inability to obtain cover in this case is simply delay: the applicant can reapply at a later point.

161. However, in general it should be presumed that the insurance and financial markets understand GM technology and its risks, and any unwillingness to underwrite a particular line of research should not be overridden without identifying who will in fact explicitly sign for the liability.

162. The Commission thoroughly miscasts the issue when it places considerable weight on an argument advanced by reinsurers, Swiss Re. The Commission states:

> In conclusion, the Swiss Re report notes that the decisive factor is not whether genetic modification is dangerous, but rather how dangerous it is perceived to be. The report concludes that the development of social and legal frameworks unfavourable to genetic modification could lead to impossibly high liability risks that cannot be carried either by the genetic modification industry or the insurance industry alone.[100] [Emphasis added]

163. The risks inherent in a technology are not changed by the legal framework. Perceptions do not alter the total risk of undertaking an activity. However, they may well alter the distribution of risk – who will carry the risk. An absence of "favour" simply means those risks remain with the industry itself. Thus the plain English translation of the Swiss Re position is that absence of an implicit subsidy could hold back GMO research. The subsidy consists of a socialisation of the costs of insuring against any damage resulting from that research.

164. 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. Government can then consider the merits of the particular case for an explicit subsidy and, if it agreed to participate, could even enter into a commercial arrangement to secure a

[100] Commission report, p. 322.

share of the benefits. Under the Fiscal Responsibility Act, the resulting contingent liability for taxpayers would then be clearly recorded in the Crown's balance sheet.

165. 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, individuals and businesses would tend to carry contingent liabilities from GMO research and release unless and until the state chooses to come to their rescue.

166. As the European Commission White Paper notes:

> "Insurability is important to ensure that the goals of an environmental liability regime are reached. … it appears that coverage of environmental damage risks is still relatively undeveloped, but there is clear progress being made in parts of the financial markets specialising in this area."

167. The White Paper puts emphasis on developing reliable qualitative and quantitative criteria for recognition and measurement of environmental damage as the way forward. It is these sciences and the further development of associated financial instruments that constitute just as necessary and important a new frontier as biotechnology.

5.2. Catastrophe Insurance and New Financial Instruments

5.2.1. Introduction

168. Substantial progress is already evident in the development of new financial instruments capable of providing cover for riskier GMO projects. GMOs are categorised as one of a number of Major Technological Risks (MTRs).[101] As noted above, GMO projects will span a range of estimated degrees of risk. However, 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 such as earthquakes, floods, and storms, all of which have been the subject of an extensive recent literature. MTRs differ from purely "natural" disasters, at first sight at least, in that damage is attributable to whatever individual or organisation was responsible for the release of the GMO, or creation of the landfill or nuclear waste facility, or manufacture of carcinogenic chemicals.

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[101] Boyer, Marcel, and B. Sinclair-Desgagné, "Corporate Governance in the Presence of Major Technological Risks, Chapter 11 in Folmer, H. et al (eds), *Frontiers of Environmental Economics*, Edward Elgar 2001.. MTRs include chemical and nuclear hazards as well as GMOs.

169. Damage arising from the taking of MTRs, thus, is not an "act of God". In acts of God the damaged party is usually also the insured, who has paid the premiums for cover, and turns directly to the insurance company for compensation following the disaster. In MTR catastrophes the damage is attributable to a primary responsible party (the party responsible for release of a GMO, for example) and damage is suffered by a third party, which puts liability at the centre of the process whereby injured parties are compensated by insurers[102].

170. Before reviewing progress in the development of new financial instruments capable of providing catastrophe cover, we first examine the nature of catastrophe risk and the insurer's perspective.

5.2.2. Catastrophes and the Failure of the Traditional Insurance Market

171. Catastrophes are events with very low probability of occurrence which cause extremely severe but largely unpredictable damage to the human economy and society. Catastrophic risks span a spectrum from "natural disasters" such as earthquakes[103], hurricanes and storms[104], floods[105] and tsunamis across to the MTRs associated with GMOs[106], pharmaceutical and medical innovations[107], nuclear power and wastes, landfills[108] and other areas of human activity with potentially major environmental consequences.

172. Traditional insurance is built on two economic principles: the risk averseness of individuals and firms, and the law of large numbers. Risk aversion means that individuals and firms are prepared to pay to avoid facing "fair gambles"; this means that provided the actual risks are known, an insurer which acts on a risk-neutral basis can make a profit by accepting fair gambles on behalf of risk-averse individuals.

173. The law of large numbers enables insurers to identify the statistically probable or expected outcome of the gambles that are taken and, by pooling the risks faced by a multitude of risk-averse individuals, to know with reasonable certainty what the insurance payouts will be to a typical population over a period.

174. Fire, motor accidents, death and illness are all susceptible to actuarial estimation of risks with a high degree of statistical confidence, and on this basis

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102 Ibid.

103 *Catastrophes: Insurance Issues Surrounding the Northridge Earthquake and Other Natural Disasters*, Insurance Services Office Inc, New York, December 1994.

104 Swiss Re, 2000, *Storm Over Europe: An Underestimated Risk?* www.swissre.com, p. 27.

105 Swiss Re, 1998, *Floods – An Insurable Risk?* from www.swissre.com, 35pp.

106 Swiss Re 1998, *Genetic Engineering and Liability Insurance: The Power of Public Perception*, Swiss Re Focus Report, from www.swissre.com, p. 12.

107 Swiss Re 1998b, *Risk Handling and Financing in Pharmaceutical Enterprises*, from www.swissre.com., p. 55.

108 Swiss Re 2000a, *Environmental Impairment Liability Insurance for Landfills*, from www.swissre.com, p. 39.

insurance against these contingencies is readily available in a well-functioning market. Key requirements for "insurability" of a risk are:[109]

- *Mutuality*: a large number of people who are at risk must combine to form a risk community;
- *Need*: when the anticipated event occurs it must place the insured in a position of financial need;
- *Assessability*: the expected loss burden must be assessable;
- *Randomness*: the time at which the insured event occurs must not be predictable and the occurrence itself must be independent of the will of the insured;
- *Economic viability*: the community organised by the insured persons must be able to cover its future, loss-related financial needs on a planned basis;
- *Similarity of threat*: the insured community must be exposed to the same threat, and the occurrence of the anticipated event must give rise to the need for funds in the same way for all concerned.

175. Catastrophic risks are difficult or impossible to insure under the traditional model because of ambiguity, low probability, unpredictability, collectivity, potential irreversibility and potential severity (scale).[110] Boyer and Sinclair-Desgagne summarise the position:

> First, catastrophic risks are difficult to measure. Their attached probabilities, being very small, cannot be estimated through empirical frequencies (unlike actuarial probabilities) and must be derived indirectly in ways that are often controversial. Their associated outcomes might also be difficult to list and describe, and it is usually impossible to agree *ex ante* on an evaluation of the damages that would hold *ex post*. Second, such risks are essentially collective. The occurrence of a bad outcome would always affect a large number of people; in other words, individual losses are correlated. Finally, catastrophes are dreadful events from which it might be impossible to recover, even to a modest extent; they entail a significant degree of irreversibility.[111]

176. The traditional insurance market is prone to fail on both the demand and the supply side, in the face of catastrophic risk. On the demand side, psychological research has demonstrated that individual judgement systematically underestimates the risks of low-probability high-damage events, leading individuals and firms both to under-insure ("it can't happen to me") and to fail to take diligent steps to minimise catastrophic risk (moral hazard).[112]

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109 Swiss Re 1998c, *Floods – An Insurable Risk?* from www.swissre.com, p.7

110 "Global Environmental Risks", Chichilnisky, Graciela, and Heal, Geoffrey, 1992, *Journal of Economic Perspectives* 7(4):65-86.

111 Boyer, Marcel, and B. Sinclair-Desgagné, "Corporate Governance in the Presence of Major Technological Risks, Chapter 11 in Folmer, H. et al (eds), *Frontiers of Environmental Economics*, Edward Elgar 2001, p. 274.

112 See: Kunreuther, Howard, "Strategies for Dealing with Large-Scale Natural and Environmental Risks", Chapter 12 in Folmer, H., Gabel, H.L., Gerking, S,. and Rose, A. (eds), *Frontiers of Environmental Economics*, Edward Elgar 2001, pp.294-300; Camerer, Colin, and

177. On the supply side, insurers are reluctant to assume catastrophic risk, including Major Technological Risks (MTRs) because

- the probabilities are incalculable as well as very low,
- outcomes are shrouded in ambiguity (unpredictability as to actual character and extent) and experimental evidence indicates that insurers are more ambiguity-averse than their customers[113];
- the sheer scale of potential insurance costs in the event of catastrophe is sufficient to test the limits even of the global reinsurance industry's resources.

178. The early 1990s were a particularly bad period for natural-disaster-related insurance claims. Two events focused attention on the rising costs of natural disaster relief: Hurricane Andrew in Florida, and the Northridge earthquake of 1994 in California. Hurricane Andrew had insured losses totalling US$15.5 billion; it has been estimated that the costs would have been US$40 billion if the hurricane had hit Miami.[114] The Northridge earthquake caused insured losses of US$12.5 billion.[115]

179. To the actual experience of huge losses from "natural disasters" was added increasing uncertainty about future climatic events as evidence of greenhouse-gas-related climate change began to accumulate, leading reinsurers such as Swiss Re to revise upwards their estimates of the probabilities of extreme events affecting densely-populated areas.[116]

Kunreuther, Howard, 1989, "Decision Processes for Low Probability Events: Policy Implications", *Journal of Policy Analysis and Management* 8(4):565-92; Kahneman, Daniel, and Tversky, Amos, 1979, "Prospect Theory: An Analysis of Risk Under Uncertainty", *Econometrica* 47:263-291, Kahneman, Daniel, Slovic, Paul and Tversky, Amos, 1982, *Judgement Under Uncertainty: Heuristics and Biases*, Cambridge University Press; Tversky, Amos, Sattah, Samuel and Slovic, Paul, "Contingent Weighting in Judgment and Choice", *Psychological Review* 101:546-567, 1988; Tversky, Amos and Koehler, Derek, "Support Theory: a Nonextensional Representation of Subjective Probability", *Psychological Review* 101: 547-584, 1994.

113 Kunreuther, Howard and Hogarth, Robin M., "Risk, Ambiguity and Insurance", *Journal of Risk and Uncertainty* 5, 1989.

114 *The Impact of Catastrophes on Property Insurance*, Insurance Services Office Inc, New York, January 1994, available on the ISO website www.iso.com/docs/stud006, p.1.

115 *The Role of Government Contracts in Discretionary Reinsurance Markets for Natural Disasters*, Lewis, Christopher M. and Murdock, Kevin C., *Journal of Risk and Insurance*, 1996, p.570.

116 Climate change is a problem because of the likelihood that existing human settlement patterns have evolved with some adaptation to the existing distribution of extreme climatic events across space. Climate change which shifts the geographical distribution of extreme events then means that events that were of little consequence in relation to previous settlement patterns become catastrophes when they begin to occur in non-adapted settlement areas.

5.2.3. New Techniques of Insuring Catastrophe Risks

180. The widely-recognised failure of traditional insurance markets in the face of Major Technological Risks is sometimes argued to leave policymakers with an unpalatable choice among banning new technologies, leaving individuals unprotected, and socialising the risks by leaving to Government the problem of compensating for damage.

181. There are, however, alternative options, built around a new class of financial derivatives which have emerged during the past decade.

182. Following the major natural disaster claims of the mid 1990s, the reinsurance industry devised new financial instruments to enable them to lay off catastrophic risks to other parties. These instruments are generically known as "catastrophe bonds".[117]

183. A catastrophe bond is a financial instrument which is issued (typically by a reinsurance company) and traded on capital markets, alongside normal bonds. The bond carries a coupon rate of return and a contingent liability that, in the event of occurrence of some specified catastrophe or category of catastrophic event, the insurance costs of the event are deductible from the principal sum. The investor thus assumes the insurer's risk in exchange for a premium rate of return on the bond.[118] A separate class of cat bonds known as "physical trigger bonds" carry liabilities which are proportional not to actual assessed losses from an event, but to the physically-measured severity of the event itself (for example, the Richter-scale severity of an earthquake).[119]

184. Individual investors could in theory be more willing than insurers to hold these relatively high-risk securities for two reasons: the risk-reducing portfolio effects of holding Insurance Linked Securities (ILRs), and the (probably) lower ambiguity-aversion of individual investors. (That is, diversified investors may well place a lower expectation of probability and severity on the events than do specialist insurers).

185. The cat bonds market developed in the 1990s as part of an explosive growth of financial derivatives in general, and because of evidence that catastrophe insurance and reinsurance contracts available from the traditional insurance

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117 See Doherty, Neil, 1997, "Innovations in Managing Catastrophe Risk", *Journal of Risk and Insurance* 64(4):713-718; *The Impact of Catastrophes on Property Insurance*, New York, January 1994, available on the ISO website www.iso.com/docs/stud006; Insurance Services Office Inc, 1996, *Managing Catastrophe Risk* New York, May 1996, available on the ISO website, www.iso.com/docs/stud001; Insurance Services Office Inc, 1999, *Financing Catastrophe Risk: Capital Markets Solutions* New York, January 1999, available on the ISO website, www.iso.com/docs/stud013; Swiss Re 1999, *Insurance Linked Securities*, from www.swissre.com, p. 29; Froot, K. (ed) *The Financing of Catastrophe Risk*, University of Chicago Press for NBER, 1999.

118 For a description of cat bonds see Swiss Re 1999, *Insurance Linked Securities*, pp.5-7.

119 Swiss Re 1999a, *Insurance Linked Securities*, from www.swissre.com, pp.9-11.

industry were overpriced relative to the available statistical evidence on actual incidence of losses, so that a potential profit opportunity existed. Doherty reports[120] work by Froot and Connell which "suggests that, over the past decade, the ratio of price minus expected losses to expected losses has been in the order 60 to 70 percent and can be much higher in high level coverages."

186. Swiss Re estimated that "in the past two years approximately $2 billion in worldwide insurance and reinsurance capacity has been created through the issuance of capital market instruments including over-the-counter swaps, exchange-traded and over-the-counter options, and private placement bonds. [These are] still small in comparison to 1997 worldwide reinsurance industry premiums of $125 billion…."[121]

187. Four cat bonds issued during 1997 and 1998 were priced at 400-450 basis points above LIBOR in a market which was still nascent.[122] One reason for the relatively low premium required to induce investors to hold these bonds is that "the occurrence of insurance-linked events is uncorrelated with the return to stocks and bonds [so that] investing in ILSs reduces the overall risk of a diversified portfolio. Indeed, if ILSs represent a limited share of an investor's overall holdings, their inclusion reduces portfolio risk by almost as much as the purchase of a risk-free security. Thus an ILS need only earn an expected rate of return slightly above the risk-free rate to improve the risk-return profile of a portfolio".[123]

188. Modelling by Swiss Re suggested that in a mature market "a 113 basis point spread would provide a sufficient incentive for investors to allocate five percent of their portfolios to the ILS… Of this amount, 100 bp would compensate for the expected loss while 13 bp would compensate for the marginally smaller amount of risk reduction achieved".[124]

189. While most cat bonds to 1999 had been for natural disasters, Swiss Re commented that "securitisation may also be attractive for some of the high-severity, low-frequency types of political risks that are now being integrated into coverage".[125]

190. Cat bonds thus represent an important example of the type of financial instrument being developed to meet the unusual insurance requirements associated with catastrophe risk.

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120 Doherty, Neil, 1997, "Innovations in Managing Catastrophe Risk", *Journal of Risk and Insurance* 64(4):714.

121 *Insurance Linked Securities*, Swiss Re, from www.swissre.com, p. 3.

122 Ibid, p. 19.

123 Ibid, p. 20.

124 Ibid, p. 21

125 Ibid, p. 23. Swiss Re has categorized GE-related risks as having a substantial political component.

5.3. Identifying Liable Parties

5.3.1. Release Permits

191. If an application is made for contained laboratory experimentation, the party to be held accountable for any third party damage is clearly identifiable. Similarly, a field trial would normally involve one party and one site. However, where an application is made for open release, the potential parties responsible for damages and the ways in which damage could arise may be numerous.

192. A pragmatic approach to ensuring that strict liability remains effective as the active parties multiply is to better define liable parties at the approval stage. That is, a single company or consortium is identified and named as ultimately responsible for damages resulting from a particular application to ERMA.

193. Once a GMO is approved for release, the party holding the approval (who will also tend to hold the intellectual property) would then be the one making any arrangements for other parties to make use of the new organism. If this applicant is made responsible for all use of the approved GMO stemming from that particular approval, ERMA's role in setting bond conditions and tracing liability would be greatly simplified. In addition, such a "single source" approach automatically provides strong incentives for accountability at all levels of use.

194. If the approval holder is ultimately liable for damage claims arising directly from a particular GMO and proposed programme, it will only make arrangements to license, franchise or otherwise distribute its commercial product to other parties under conditions that take account of its ultimate liability. There will be strong commercial incentives not only to ensure that any agent with which it contracts exercises due care, but also that such franchised users of the technology accept liability conditions consistent with their role in the distribution chain. Further, the insurer (and reinsurer) standing behind the applicant will have incentives to maintain supervision over any subcontracting arrangements in order to protect their position.

195. Thus the single source model quite naturally generates the appropriate cascade of contract and accountability arrangements without ERMA needing to interfere with or track each of these dealings. The requirement ERMA would need to impose is one of prior notice of significant changes of scope and scale in the intended use of the GMO, to allow for a review of the level of performance bond required. The bond level should also be reviewable as a result of information received from the approval holder concerning performance in the field, such information already being required under the HSNO Act.

196. The prospect that the single source model also needs to accommodate is multiple parties releasing the same GMO. Under current HSNO Act requirements, once a particular GMO has been approved for release, no other party need seek authorisation before releasing it also. The new GMO is added to

the Act's schedules and from that point, any party may freely use it. Thus ERMA currently gets only one chance to impose conditions and requirements tied to open release. The realities of assigning liability for GMO-related damages suggest it would be desirable to instead shift to individual permits for initial and all subsequent releases of any GMO.

197. This points to a change in the form of the approval that ERMA would issue. Rather than ERMA simply deciding on the question of whether a GMO can be released, ERMA would consider whether each particular applicant should be granted a release permit. In order to obtain such a permit, the applicant would need to lay out its planned programme for distribution of the GMO upon release.

198. Ideally, the applicant would also be the holder of intellectual property rights to the GMO for New Zealand (or would have the intellectual property holder linked as part of a consortium making the application). A feature of genetic modification is that individual GMOs are almost invariably protected by intellectual property rights. By the time an application is made for open release, a patent application would have been filed or a patent would already be held. The reason for this is clear. Genetic modification is relatively expensive to undertake. If the target of the research is commercialisation of a particular GMO, then the only way of ensuring a payback on the research is to gain intellectual property rights on the new GMO so as to protect against others making unauthorised use of the intellectual property once the GMO is released.

199. To the extent the applicant possesses exclusive intellectual property rights to the GMO in question, it could be granted an exclusive permit by ERMA. Economic incentives should be devised to encourage such applications as there would be considerable advantages to ERMA from dealing on an ongoing basis with just one party in respect of a GMO. However, if a second party with overlapping intellectual property rights wishes to also market the same GMO, that party would seek a separate permit that would specify its development plans. Each party would then be the single liable source for its own set of activities insofar as they could be separately identified and monitored. To the extent that a damages claim arose under circumstances where neither of the two parties believed they were responsible, strict liability would have the effect of making all parties holding authorisations for the relevant GMO jointly and severally liable.

5.3.2. Rogue Release and Other Design Issues

200. There are a host of detailed design issues to be addressed when implementing a compulsory liability insurance requirement. These include:

- Ensuring local insurers have unrestricted access to the international reinsurance market. Reinsurance is important principally because of the risk that local insurers, having small assets relative to many overseas firms, might themselves be unable to meet a very large claim. However, international discipline is also necessary to make the coverage fully contestable and not

give market power to local firms as a result of compulsory insurance requirements.

- Considering how to improve the flow of relevant information, for example by setting information disclosure regulations, to assist the monitoring of GMO developers by insurers and ERMA. This would include monitoring of preventive measures adopted and ongoing financial fitness. It would allow the tailoring of initial contract conditions and potential revisions or warnings.

- Ensuring the design of the institutional framework minimises the opportunities for potential victims to strategically position to gain compensation through contributory negligence.

- Considering how to provide backup sources of funding should liability insurance fail through an exclusion in the policy – such as gross negligence. For example, ERMA could be given the power to require a form of security that was in effect a charge over intellectual property rights held by the company, it parents or affiliates.[126] These would be called on only to the extent that insurance cover did not meet the damages claims. This also points to the need for ERMA to ensure the terms of any policy submitted as part of an application pass minimum conformance tests.

- Examining how to reduce the potentially high litigation costs involved for victims seeking to prosecute for damages (which apply even where strict liability, compulsory insurance and "single source" permitting are in place). One possibility is establishing procedures which facilitate bounty-hunting by private enforcers.[127]

201. Perhaps the most difficult design issue is how to combat incentives to evade regulatory disclosure and compulsory insurance by engaging in illegal (rogue) release of new organisms.[128] The unauthorised release of the rabbit calicivirus was a clear demonstration of the potential for rogue releases of new and exotic organisms into the New Zealand environment.

202. As already noted, GMOs are the product of deliberate research on which a commercial return can be secured only once the GMO is released. Key issues are how to prevent illegal release for private gain[129], and how to allocate liability for

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126 As relevant patents may be held overseas, this would need to be an instrument that was enforceable locally.

127 See Tietenberg, Tom and Wheeler, David, "Empowering the Community: Information Strategies for Pollution Control", Chapter 4 in Folmer, H. et al (eds) *Frontiers of Environmental Economics*, Edward Elgar, 2001, pp.101-102; Naysnerski, W. and Tietenberg, T., "Private Enforcement of Environmental Law", *Land Economics* 68(1):28-48, 1992.

128 For a discussion of such evasion in the case of waste disposal see Sigmsan, Hilary, "Midnight Dumping: Public Policies and Illegal Disposal of Used Oil", *RAND Journal of Economics* 29(1):157-178, Spring 1998.

129 Possible examples range from unauthorised planting of modified seeds by individual farmers, to deliberate sabotage by GM competitors seeking to discredit a particular GMO or to expose

damage resulting from rogue release in cases where such release is covert or untraceable.

203. The HSNO Act criminalises the deliberate release of any GMO not authorised by ERMA. However, as with the calicivirus, the releaser may never be identified. Thus preventative action must also focus on denying the releaser any opportunity for commercial gain and devising new regulations to provide for this if the existing are not adequate to the task.

204. The further question is how to allocate liability if no releasing agent can be identified? The first line of defence is that patent-holders and any other authorised New Zealand users of the technology should be obliged to demonstrate that they should not be liable for damage caused by rogue release of "their" GMOs. While less than a full presumption of liability, such a requirement is necessary to incentivise legitimate firms to undertake policing and supervision of the use and release of their authorised technologies.

205. Rogue release is unlikely to be covered by insurance as either the illegal act would void the insurance cover or else the releasing agent has no insurance to begin with. For the Government to assume liability for damages from rogue release would simply open the way to opportunistic behaviour by both biotechnology firms and third parties. For damages to lie with third parties would be grossly unfair and again would open the way to opportunism by GMO developers.

206. Any solution should therefore involve a mechanism by which the GM industry funded damages that could not be recovered. The precedent is the US Superfund which taxes a range of industries to provide cover for cleanup costs that can not be allocated to responsible parties (see section 4.3). A more broadly based tax and coverage policy such as the Superfund would seem preferable if this approach is to be applied. However, although it should be possible to improve considerably on the US experience with this model, it will remain a difficult option to implement successfully.

5.3.3. Biodiverstiy and Crown Contingent Liabilities

207. The Government has clear financial incentives to explore solutions not just to protect against rogue release, but adverse effects in general. 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.

208. The Cartegena Protocol on Biosafety to the Convention on Biological Diversity, to which New Zealand has indicated it will become a signatory, contains the following obligations under Article 16.

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its owner to crippling damage suits – "raising rivals' costs", to use a term familiar from antitrust law.

> 1. The Parties shall, taking into account Article 8(g) of the Convention, establish and maintain appropriate mechanisms, measures and strategies to regulate, manage and control risks identified in the risk assessment provisions of this Protocol associated with the use, handling and transboundary movement of living modified organisms.
> 2. Measures based on risk assessment shall be imposed to the extent necessary to prevent adverse effects of the living modified organism on the conservation and sustainable use of biological diversity, taking also into account risks to human health, within the territory of the Party of import.

209. While there are considerable uncertainties surrounding the valuation of ecological resources, increasingly their value is being formally recognised through new accounting conventions. As noted earlier, the EU White paper formally recognises biodiversity as a category of damages for which strict liability should apply and proposes the following approach for the estimation of damages.

> If restoration is technically not or only partially possible, the valuation of the natural resource has to be based on the costs of alternative solutions, aiming at the establishment of natural resources equivalent to the destroyed natural resources … .[130]

210. Whatever approach is selected for valuation of 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. As such, the Fiscal Responsibility Act arguably requires that these be accounted for. In particular, section 10 (3) (b) of the act states:

> The forecast financial statements for the Crown shall also include:
> (a) … :
> (b) A statement of specific fiscal risks of the Crown as at the day on which the forecast financial statements are finalised, being the fiscal risks in relation to
> (i) The Government decisions and other circumstances required by section 11 of this Act to be incorporated in the economic and fiscal update; and
> (ii) Any other contingent liabilities of the Crown, including any guarantees or indemnities given under any Act:

211. Thus the Crown has a clear incentive to ensure that private parties bear the full risks of GMO development so that contingent liabilities appear on the books of developers, rather than on the Crown's accounts.

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130 *White Paper on Environmental Liability*, European Commission, February 2000, p. 20

6. Liability Law Reform in Other Jurisdictions

Before examining in more detail the existing New Zealand liability regime, we turn to look at the parallel liability frameworks in other familiar jurisdictions.

6.1. United Kingdom

212. The EU has tended to opt for a penal approach to the question of specific liability for GMO use. This is responsive in part to the polluter pays principle, to deterrence objectives and to normative principles linked to some measure of criminalisation of environmental harm. The Council for Europe's Convention on the Protection of the Environment through Criminal Law was signed on 16 November 1998 by seven nations, including EU member states Denmark, Finland, France, Germany, Greece and Sweden. Austria, Belgium and Luxembourg signed in 1999. Pollution is criminalised. Possible penalties include imprisonment, fines, restoration of the environment, confiscation of profits and corporate liability. Until the EU harmonises criminal law, the Convention must be adopted only at the EU member state level. A "penal" approach to questions of environmental liability appears to influence much of the EU response to these questions.

213. The penalties regime pursuant to Council Directive 2001/18/EC is to be located at Article 33 concerning the deliberate release of a GMO or a combination of GMOs and stipulates:

> Member States shall determine the penalties applicable to breaches of the national provisions adopted pursuant to this Directive. Those penalties shall be effective, proportionate and dissuasive.

214. Article 33 seems to reflect not only the language of criminalisation (use of the term "penalties" is much more suggestive of culpability than mere liability) but also deterrence ("dissuasive", for example).

215. Also established under the directive is a requirement to undertake comprehensive environmental risk assessment (see Annex II) which includes compulsory monitoring plans for cumulative long-term effects on human health and biodiversity (both agricultural and non-agricultural) after release. Member states are obliged to trace and identify any direct or indirect, immediate, delayed or unforeseen effects from GMOs.

216. It is still too early to determine how the member states will respond to Article 33 under the new Directive. However, a British Consultation Paper on the Implementation of Directive 2001/18/EC on the Deliberate Release into the Environment of Genetically Modified Organisms (July 2001) refers to existing penalties established pursuant to the United Kingdom's implementation of Directive 90/220/EC and hints that those penalties may be considered satisfactory.

The present United Kingdom approach is to be found in Part VI of the Environmental Protection Act 1990 (UK) and in the associated Genetically Modified Organisms (Deliberate Release) Regulations 1992, as amended in 1995 and 1997 respectively.[131]

217. Inspectors are appointed under the Environmental Protection Act (UK) to enforce the GMO provisions (section 114 of the Environmental Protection Act (UK)).

218. The United Kingdom Parliament requires persons involved in the release of GMOs to actively monitor the potential damage to the environment, including the property of others. Section 109(4) of the Environmental Protection Act (UK) specifically imposes mandatory duties for any person proposing to release GMOs:

> A person who proposes to release genetically modified organisms –
> (a) shall take all reasonable steps to keep himself informed, by reference to the nature of the organisms and the extent and manner of the release (including any precautions to be taken against their causing damage to the environment), what risks there are of damage to the environment being caused as a result of their being released;
> (b) shall not release the organisms if it appears that, despite the precautions which can be taken, there is a risk of damage to the environment being caused as a result of their being released; and
> (c) subject to paragraph (b) above, shall use the best available techniques not entailing excessive cost for preventing any damage to the environment being caused as a result of their being released;
>
> and this subsection applies, with the necessary modifications, to a person proposing to market organisms as it applies to a person proposing to release organisms.

219. "Damage to the environment" is defined under section 107(3) of the Environmental Protection Act (UK) and reads:

> "Damage to the environment" is caused by the presence in the environment of genetically modified organisms which have (or of a single such organism which has) escaped or been released from a person's control and are (or is) capable of causing harm to the living organisms supported by the environment.

220. "Harm" under section 107(6) of the Environmental Protection Act (UK), "means harm to the health of humans or other living organisms or other interference with the ecological systems of which they form part and, in the case of man, includes offence caused to any of his senses or harm to his property [emphasis added]."

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131 Genetically Modified Organisms (Deliberate Release) Regulations 1995 and the Genetically Modified Organisms (Deliberate Release and Risk Assessment – Amendment) Regulations 1997 (UK).

221. The offence provision for the above subsection is located at section 118 of the Environmental Protection Act (UK). Section 118(1)(d) stipulates that:

> It is an offence for a person –
>
> (d) to fail to comply with any requirement of subsection (2), (3)(a), (b) or (c) or (4) of section 109 above in relation to something which is, and which he knows or has reason to believe is, a genetically modified organism; …

222. A person found guilty of an offence under section 118(1)(d) is liable on summary conviction to a fine not exceeding £20,000 or to imprisonment for a term not exceeding six months or both. On conviction on indictment, that person is liable to a fine or to imprisonment for a term not exceeding five years or both (refer to section 118(3) of the Environmental Protection Act (UK)). Under section 112(4) of the Environmental Protection Act (UK) certain conditions are implicitly imposed on any consent given for keeping GMO:

223. The United Kingdom Government has largely opted for fines. This is not an uncommon regulatory mechanism and the British have proved to be particularly fond of it in schemes designed to ensure compliance and to carry a punitive element as well as endeavouring to ensure the accomplishment of performance targets or preferred behaviours generally. An example is the ability since 1 March 2000 of the Office of the Rail Regulator established under the Railways Act 1993 (UK) to impose fines not exceeding 10 percent of turnover.[132]

224. On 17 February 1999, the United Kingdom Government levied its first fines for breach of the Environmental Protection Act's GMO provisions. After Monsanto and its British subcontractor Perryfields Holdings pleaded guilty to the breach, the Government imposed fines of £17,000 and £14,000 respectively. An inspector had found that the companies had violated the six-metre border requirement established as a condition of granting consent. The actual border between the GMO crops and adjoining crop plantations was merely two metres in width, engendering a risk of contamination through cross-pollination. Monsanto and Perryfields Holdings as the consent holders were held liable. No damage to the non-GMO crops had occurred. At this stage, we have not been able to locate any *judicial* authority on GMOs causing damage in the United Kingdom setting.

225. What is noticeable is that the United Kingdom has assumed "a proactive approach to improving the assessment of longer-term risks from releases of GMO crops into the environment."[133] The United Kingdom Government and the plant breeding industry through the industry representative body SCIMAC (Supply Chain Initiative on Modified Agricultural Crops) agreed in November 1999 on the conduct of farm scale evaluations of GMO crops, to cover the three years through

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132 Transport Act 2000 and Competition Act 1998 (UK). Office of the Rail Regulator, *Accountability of Railtrack* (May 2001).

133 OECD, *Report of the Working group on Harmonisation of Regulatory Oversight in Biotechnology* (Paris, 25 May 2000), "Farm-Scale Evaluations in the United Kingdom", pp. 43-44.

to the harvest of crops planted in 2002. The expectation is that sufficient data will be collected for an appraisal of the GMO crops on the environment.

226. Civil liability for GMOs causing damage to property exercises political concern however. Alan Simpson MP (Labour, Nottingham South) introduced the Genetically Modified Food and Producer Liability (No. 2) Bill 2000 to the House of Commons in November 2000. Although it was not a Government Bill, the Bill passed its first reading. The House of Commons has advised us (as at 9 August 2001) that the Bill was scheduled for its second reading on 24 November 2000 but this never occurred. It must be noted that some senior Labour MPs, such as Dr Jack Cunningham, voted against its introduction. The Christmas recess then intervened and with the press of Government business (including the foot and mouth crisis) and the dissolution of Parliament before the June general election the Bill seems to have faltered for the time being.

227. The Food Team of Friends of the Earth (England, Wales and Northern Ireland) were behind the Alan Simpson campaign in support of the Genetically Modified Food and Producer Liability (No. 2) Bill. That Team (and especially Peter Roderick, Legal Advisor to Friends of the Earth) participated in the design of the Bill.

228. Clause 2 of the Bill establishes a framework for civil liability and reads as follows:

> (1) A person (in this Act referred to as a "potential defendant") who –
>
> (a) holds a consent under section 111 of the Environmental Protection Act 1990 (consents required by certain persons); or
> (b) holds a consent given by another Member State under Article 13(4) of Council Directive 90/220/EEC on the deliberate release into the environment of genetically modified organisms
>
> shall be liable for any damage which is caused by deliberate release or marketing of a genetically modified organism under the terms of that consent.
>
> (2) Where liability under this section is incurred by a body corporate any director, manager, secretary or other similar officer of the body corporate shall be similarly liable unless he can show that he did everything in his power to prevent the deliberate release or marketing which caused the damage in question; and in this Act any reference to a potential defendant shall include reference to such a director, manager, secretary or other similar officer.
>
> (3) Where damage to the environment outside the meaning of paragraphs (a) to (d) of section 3(1) occurs –
>
> (a) the Secretary of State; or
> (b) with leave of the court, any other person

> may apply to the court for damages to be awarded against a potential defendant.
>
> (4) In reaching its decision on an application under subsection (3) the court may have regard to such matters as seem to it to be relevant, including –
>
> (a) the severity and detrimental effect of the damage to the environment;
> (b) any relevant profits made by a potential defendant; and
> (c) any relevant remuneration received by a potential defendant.

229. A reverse onus of proof is introduced *via* the proposed section 4 of the Bill. It is up to the person proceeded against to "prove that he did not cause the damage in question [clause 4(1)]." The rather extreme defence of an "exceptional case of force majeure" is introduced at clause 4(3) of the Bill. There is no other defence.

230. Insurance is dealt with under clause 6 of the Bill which criminalises the failure to acquire specific insurance.

231.

> (1) A potential defendant shall take out a policy of insurance against liability to pay compensation for damage.
> (2) A person who fails to comply with the requirements of subsection (1) shall be guilty of an offence ad shall be liable –
>
> (a) on summary conviction, to a fine not exceeding level 3 on the standard scale;
> (b) on conviction on indictment, to a fine not exceeding level 5 on the standard scale or to a term of imprisonment not exceeding 3 months or both.

232. There are several recent matters in the United Kingdom which might have an impact on this overall area. The image of a moving feast comes to mind. On 9 August 2001, 10 Downing Street announced three independent inquiries into the foot and mouth disease crisis. In terms of the persons to whom the inquiries will report, it is clear that the Government intends to be seen as acting seriously on the broad policy issues as well as the specific questions of the crisis. The inquiries which will report to the Prime Minister and the Secretary of State for Environment, Food and Rural Affairs are:

(a) Inquiry into the lessons to be learned from the foot and mouth disease outbreak of 2001 and the way in which the Government should handle future major animal disease outbreak, to be chaired by Dr Iain Anderson;

(b) Scientific Review by the Royal Society of questions relating to the transmission, prevention and control of epidemic outbreaks of infectious disease in livestock, committee to be chaired by Sir Brian Follett FRS;

(c) Policy Commission of the Future of Farming and Food. The Policy Commission will "advise on how to create a sustainable, competitive and diverse farming and food sector within a thriving rural economy which

advances environmental, health and animal welfare goals."[134] It has been asked to report by the end of 2001.

233. Lord Haskins has been appointed as Blair's Rural Recovery Co-ordinator to assist local authorities and other agencies plan for the recovery of Cumbria, the area worst affected by the foot and mouth disease crisis. He will also consider broader lessons applicable to other areas.

234. The United Kingdom Government is moving on the issue of GMO liability. In doing so, it is apparently concerned about the possibility of being judicially reviewed by biotechnology industries in the event of an implementation of EC Directive 2001/18/EC that favours "Green" and allied non-biotechnology interests. Conversely, it is concerned about irritating "Green" and allied non-biotechnology interests such that it attracts judicial review actions from that quarter. Friends of the Earth for England, Wales and Northern Ireland has been invited by the Blair Government to participate in the preparation of policy papers on GMO liability questions. The Real Food Campaign of Friends of the Earth has advised us that it refused this request and recommended that the Government produce a paper which they could then critique.

6.2. United States

235. The United States does not have a comprehensive regulatory scheme addressing the question of specific liability for GMO use. Instead, it has adopted a piecemeal approach to regulation of GMO use in general. As a result, regulation is spread between various agencies at the federal level – in particular the United States Department for Agriculture (responsible for ensuring GMOs are safe to grow), the Food and Drug Administration (responsible for ensuring that GMOs are safe to eat) and the Environmental Protection Agency (responsible for overseeing the use of new companion herbicides for GMOs and for ensuring that GMOs are safe for the environment).[135]

236. Neither the agencies involved in biotechnology regulation nor private citizens are able to use the various federal laws that regulate biotechnology to impose liability for, or to recover for, GMO-caused damage. Consequently, claimants in the United States must rely wholly on the common law doctrines of trespass, negligence, strict liability or nuisance for a remedy.

237. The application of the common law doctrines is elusive in relation to liability for GMO use. As yet, there are no clearly decided cases in the United States establishing how and when common law liability for GMO use will attach. Commentators have to date concentrated their discussion on how the common law doctrines *may* be utilised and argued in the Courts, but there appears to be much uncertainty about what level of liability will prevail.

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134 10 Downing Street, press release, 9 August 2001, www.number-10.gov.uk.

135 A. Bryan Endres, "'GMO': Genetically Modified Organism or Gigantic Monetary Obligation? The Liability Schemes for GMO Damage in the United States and the European Union" (2000) 22 *Loy. L.A. Int'l & Comp. L. Rev*. 453, 479-80 (Hereinafter "GMO Liability").

238. One commentator has argued that an action in trespass would seem to apply to GMO "pollen, plant seeds or pests which are wind blown from a neighbouring landowner's property onto plaintiffs' property. The plaintiffs would have the burden, however, of showing that the presence of GMOs interferes with the exclusive possession of their property, that the defendant's acts caused the GMOs to invade their property, and that the GMOs have caused substantial damage to their property."[136] The difficulty with this line of argument is that it may be hard to prove causation – particularly that any contamination came from a particular defendant.

239. Likewise, under conventional nuisance doctrine, causation could prove problematic. To establish a nuisance claim it will be necessary to show that GMO contamination arising from a particular defendant caused interference with the plaintiffs' use and enjoyment of their property.[137] However, the causation issue is not insurmountable. In *Lunda v Matthews*[138], a case involving landowners who had built their house six years before the defendants built a cement plant on nearby industrial land, the Court cited such factors as "the proximity to the plaintiffs' home, the frequency of the intrusion, the original character of the area in which the defendant's plant was located and the limitations the intrusion placed upon the plaintiffs' use of their property" to conclude that there was sufficient evidence to establish the existence of a private nuisance.[139]

240. One further potential difficulty with nuisance claims in the United States could arise from application by the Courts of a social utility balancing test when deciding on what relief to grant in a GMO contamination case. Factors such as the social value in food production, investment in production of GMO crops and consequential damages could all come into play, to an uncertain outcome.[140]

241. However, some claim that the boon of the public nuisance tort in particular is that it allows the Government and sometimes even private individuals to enjoin activities and recover damages for "unreasonable interference with a right common to the general public." The key to a public nuisance claim arising from GMO contamination is that the contamination be "unreasonable" and the injury is to the general public, not just to the farmer whose crops have been affected.[141]

242. For an action in negligence to succeed in the United States it is necessary to prove five core elements: a duty of care, breach of that duty, factual causation between the breach and the injury, proximate causation between the breach and the injury, and actual injury. The most difficult ingredient when seeking to sustain a negligence theory claim for damage caused by GMO contamination will be

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136 Richard A. Repp, "Biotech Pollution: Assessing Liability for Genetically Modified Crop Production and Genetic Drift", (2000) *36 Idaho L. Rev.* 585, 602-3 (Hereinafter "Biotech Pollution").

137 "Biotech Pollution", at 607.

138 613 P. 2d at 66-67, cited in "Biotech Pollution", at 608.

139 "Biotech Pollution", at 609.

140 "Biotech Pollution", at 611-12.

141 "GMO Liability", at 491-2.

establishing that a duty of care exists. Establishing a foreseeable likelihood of harm could be one area of trouble: it would be necessary to prove that the scientific studies exist to document GMO risks and injuries. Once a duty of care has been proven, establishing that the defendant breached that duty could also present an additional hurdle.[142]

243. Finally, GMO contamination may fall within the scope of a strict liability claim: "planting GM crops may qualify as an abnormally dangerous activity. Because a GM crop producer will have difficulty controlling pollen, wind blown seeds, and pests once they enter an ecosystem, if the plaintiffs present sufficient evidence of the destructive capacity of the GMOs a court may decide strict liability analysis is appropriate."[143]

244. The case of *Langan v Valicopters, Inc*[144] provides some insight into how a strict liability theory might run for GMO contamination. The *Langan* court followed the six-point analysis dictated by the Restatement (Second) of Torts[145] in deciding that the defendant should be held strictly liable for damage to a neighbour's crops from aerial spraying of pesticides. Following that analysis in a GMO case, a court could conclude that:[146]

> (1) growing GM crops involves a high degree of risk of harm because of the impossibility of eliminating the risk of genetic drift from pollen, plant seeds, and pests; (2) the gravity of harm to a non-GM grower could be very damaging because of market restrictions and/or crop failure; (3) the uncontrollability of genetic drift can not be entirely eliminated even after establishing recommended buffer zones and otherwise exercising reasonable care in the production of GM crops; (4) although GM production may be the dominant production method in a particular area, it might not qualify as a matter of common usage because the total number of GM producers represent a minority of all farmers; (5) land adjacent to an organic farm or other non-GM farm is an inappropriate place for GM crop production because of the risk of contaminating the non-GM crops; and (6) despite the socially valuable goals of increasing food production and controlling insects, weeds, and other pests without applying pesticides, an "equitable balancing of social interests" would require a GM crop producer to pay the consequences of the production activities that cause damage to neighbouring farmers.
> [Footnotes omitted]

6.3. Australia

245. The Gene Technology Act 2000 (Cth) applies in Australia. Liability for property damage or economic loss is not dealt with specifically in the Gene Technology Act. The Commonwealth component of the Gene Technology Act

142 "Biotech Pollution", at 615-6.
143 "Biotech Pollution", at 618.
144 567 P. 2d at 222.
145 Restatement (Second) of Torts, § 520(a)-(f) (1965), as cited in "GMO liability", at 488.
146 "Biotech Pollution", at 619-20.

was expected to be operational by 21 June 2001. The Gene Technology Act covers the entire life cycle of a modified organism, from research in laboratories, growth, development and production or manufacture of GMOs. It also covers issues such as transport, import and disposal of GMOs.

246. Whilst the Gene Technology Act evinces an intention to regulate all dealings with GMOs across Australia through relying on a number of constitutional powers reserved for the Commonwealth, the national regulatory regime for GMOs requires each state and territory to enact corresponding laws before the Commonwealth regime is fully operative. The scheme is underpinned by a Gene Technology Intergovernmental Agreement (IGA) that will come into effect once it has been signed by at least three states and one territory.

247. The Office of Gene Technology Regulator was established under the Gene Technology Act.

7. The Current Liability Framework

This section reviews the principal statutes and case precedents that set the current liability regime that could be expected to apply to GMOs.

7.1. Hazardous Substances and New Organisms Act 1996

248. The Hazardous Substances and New Organisms Act 1996 (HSNO) is the principal statute governing GMOs. The act does not take a strategic approach to regulating genetically modified crops and possible damage to property. HSNO instead provides for ERMA to respond to GMO developments through assessing applications as they are submitted on a case by case basis.[147] Specific notions of liability regarding the various possibilities of "damage" to which legal liability may or may not attach is ill-formed and overly dependent upon conventional conceptions of tortious liability. The objective of any liability measures in novel arenas, including those associated with GMOs, ought to be ensuring compliance with rigorous risk assessment approaches to proposed field trials or releases of GMOs.

249. A detailed account of the relevant offence provisions in HSNO is attached as Appendix I. The two key points that have shaped the act are as follows:

(a) It is not the creation of the adverse environmental effects *itself* which is an offence under HSNO, but the breach of the statutory approval regime.

(b) The emphasis within HSNO is on front-end risk assessment rather than on responsibility for any harm to persons or property *per se*.

7.1.1. Interpretation of HSNO

250. Not surprisingly, therefore, litigation in the arena of GMOs has often just addressed the question of whether the agency charged with considering applications for the research, testing or release of GMOs has complied with statutory procedures. That is, judicial review applications, declaratory judgements or appeals on points of law are in general evidence under specific legislative

147 For an illustration of this approach in practice refer to *Bleakley v Environmental Risk Management Authority* [2001] 3 NZLR 213 (HC). Environmental risk assessment tends to operate internationally on this case by case basis (for example, the Objective of "environmental risk assessment" under Annex A to Directive 2001/18/EC of the European Parliament and Council) but it would be constructive to design a strategic approach to liability issues that ensures rigorous risk assessment through the "deterrence" objective or effect.).

regimes addressing genetically modified crops or animals, but not assertions of economic loss and damage per se.[148]

251. The first judicial pronouncement on the operation of the GMO provisions within the Environmental Protection Act 1990 (UK) provides a relevant example – *R v Secretary of State for Environment and Ministry of Agriculture Fisheries and Food, ex parte Watson*.[149] An application for judicial review was involved. Watson, the applicant for judicial review, was an organic farmer producing vegetables including sweet corn. A trial planting of genetically modified maize on an adjoining farm caused him concern. He feared that there was a risk that the maize would cross-pollinate with his organic crops and would threaten his accreditation as an organic farmer.

252. Sharpes, a major international corporate grower of seed types, was responsible for the trial planting of a type of maize known as T-25 under the Seeds (National Lists of Varieties) Regulations 1982 (UK). The maize was planted at a site owned by the National Institute of Agricultural Botany under an arrangement with the second respondent, the Ministry of Agriculture Fisheries and Food through the British Society of Plant Breeders. The consent to release the maize into the environment was granted to Sharpes under section 111 of the Environmental Protection Act 1990 (UK).

253. Watson learned of the trial planting and the Soil Association of Great Britain informed him of the threat to his accreditation and status as an organic farmer. Subsequently, Watson moved his sweet corn crop away from the trial site (two-kilometre distance). No damage was alleged to have occurred. Watson's solicitors advised the respondents that the trial should not be commenced and the respondents then sought advice from the Advisory Committee on Releases to the Environment (ACRE). ACRE reported that a distance of two kilometres reduced the risk of cross-pollination to a likely zero chance. On that ground the respondents notified Watson that they had decided not to revoke or vary the consent given to Sharpes. Watson sought to challenge that decision via judicial review. He did not succeed.

254. The challenge to the ACRE advice was on the basis of irrationality, a very difficult ground to establish against official agencies in judicial review hearings. The English Court of Appeal held that although the ACRE report advised that "the amount of cross-pollination is likely to be zero", it could not regard such a stance as an irrational decision. Lord Justice Simon Brown stated:

> [The "risk point" claim] is advanced as an irrationality challenge and is directed to the Department's reliance in their decision letter upon ACRE's advice that "the amount of cross-pollination is likely to be zero". This submits Mr Fordham [counsel for Watson], is too narrow an approach, which does not adequately address the actual degree of risk nor the

148 E.g. *R v Secretary of State for Environment and Ministry of Agriculture Fisheries and Food, ex parte Watson* [1999] Env. LR 310 (UKCA) (judicial review); *Bleakley v Environmental Risk Management Authority* [2001] 3 NZLR 213 (HC) (appeal on question of law).

149 [1999] Env LR 310 (UKCA).

> consequences were that risk to eventuate. If cross-pollination occurs, it will have a devastating effect upon the applicant's business, reputation and livelihood. The Soil Association take an absolute stance with regard to accreditation. Not merely would the organic status of the applicant's present sweet corn crop be imperilled; so too would the rest of his farming enterprise.
>
> Grave though I accept the consequences of contamination here would be, and understandably worried though the applicant must be, I cannot regard this as an irrational decision.[150]

255. Lord Justice Simon said that the ACRE advice must be read in context. Competing interests had to be considered and the Court of Appeal believed that ACRE balanced interests (incompatible uses) rationally. This is of interest as there may be occasions where property damage occurs even though a reasonable balancing of interests has occurred and the approval agency (ERMA) has granted permission for release – would the damage be recoverable at law and, if so, who should pay? A passage from the judgement shows how this was done:

> Let me quote three short paragraphs [from the ACRE advice]:
> "Under conditions which would maximise cross-pollination (the worst case scenario) ACRE accepted that 1sweetcorn kernel in every 1,000 could be a GM hybrid (this is equivalent to Basic Seed 99.9% purity). In reaching that conclusion ACRE assumed that all pollen being transferred to the organic sweetcorn was GM, that the sweetcorn and the GM maize flowered at exactly the same time and the wind was in the most appropriate direction.
> Conversely, under the conditions which would minimise cross-pollination then no cross-pollination would occur. For this to happen, the GM maize and the sweetcorn must not flower at the same time, in which case the short life of maize pollen would mean that a significant amount could not remain active in the environment to pollinate sweetcorn later.
> Having established the upper and lower limits for cross-pollination, ACRE then asked what level of cross-pollination was most likely to actually occur at 200 metres in the Devon situation? This was estimated to be no greater than 1 GM hybrid kernel in every 40,000."
> In the context of those paragraphs it seems plain to me that the assurance then given in respect of the actual two km. separation between the respective crops s not merely to be regarded as an assessment of risk but as a reasonably confident assessment that realistically there is no more than minimal risk. Of course, this falls short of the guarantee which the applicant and Friends of the Earth were looking for. But it seems to me a perfectly reasonable point to strike the balance between the competing interests in play. Whether events prove the assessment to have been too sanguine remains to be seen. That, however, as all parties before us recognise, is not a matter for this Court.

256. It is unsurprising that the Court was unwilling to interfere with the policy adopted on the part of ACRE. The Court will look at the risk assessment on public law grounds only and will not make any adjudication on the substantive

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150 *Ibid*, at 315-316.

acceptability of the policy advice.[151] The case leaves open the question of what occurs when damage does arise and it is important to understand the case as a judicial review application. One commentator referring to the *Watson* case has stated that "[p]rior restraint in the form of judicial review of an authorisation decision has proved to be ineffective."[152]

257. Before turning to possible areas of liability at common law, we consider liability arising under the Resource Management Act 1991 and cover provided for personal injury under the accident compensation regime.

7.2. The Resource Management Act 1991

258. Liability for damage arising from use of GMOs may also arise under the Resource Management Act 1991 (RMA). The main source of potential liability is section 17. Under section 17(1), every person has the 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." A conditional release programme for GMOs would constitute an activity with the potential for adverse effects on the environment. As such, any person involved in the programme will have 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.

259. However, section 17(2) is explicit that this duty is not itself enforceable against any person and that no person will be liable to any other person for a breach of that duty.

260. Instead, the RMA provides that an "abatement notice" or an "enforcement order" may be made to require a person to cease or not commence anything that is or is likely to be "noxious, dangerous, offensive, or objectionable to such an extent that it has or is likely to have an adverse effect on the environment" or to do something that is "necessary in order to avoid, remedy, or mitigate any actual or likely adverse effect on the environment" (section 17(3)).

261. The term "environment" is defined under section 2 to include:

(a) Ecosystems and their constituent parts, including people and communities;

(b) All natural and physical resources;

(c) Amenity values; and

(d) The social, economic, aesthetic, and cultural conditions which affect the matters stated in paragraphs (a) to (c) of this definition or which are affected by those matters.

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151 See also *Bleakley v Environmental Risk Management Authority* [2001] 3 NZLR 213 (HC).

152 A Waldron, "Transgenic Torts", (1999) *JBL* 395, 395.

262. It is significant that any adverse effects and potential liability arising therefrom are limited to effects on the environment. No liability will arise under the RMA for personal damage or loss suffered by an individual.

263. The term "effect" is also extensively defined under the RMA to include any positive or adverse effect, any temporary or permanent effect, any past, present, or future effect, and any cumulative effect which arises over time or in combination with other effects, regardless of the scale, intensity, duration, or frequency of the effect. "Effect" also includes any potential effect of high probability and any potential effect of low probability which has a high potential impact.

264. The RMA contains broadly detailed provisions about the scope of both abatement notices and enforcement orders. Abatement notices are the first step in creating liability for contravention of the RMA by use of GMOs. An abatement notice may be served on any person by an enforcement officer and require, for example:

- that person to cease or not commence anything that contravenes or is likely to contravene the RMA or that is likely to be noxious, dangerous, offensive, or objectionable to such an extent that it has or is likely to have an adverse effect on the environment.

- that person to do something that is necessary to ensure compliance with the RMA, and also necessary to avoid, remedy, or mitigate any actual or likely adverse effect on the environment.

265. Enforcement orders are made by the Environment Court under section 319 , and may:

- require a person to cease or not commence anything that contravenes or is likely to contravene the RMA, or anything that is or is likely to be noxious, dangerous, offensive, or objectionable to such an extent that it has or is likely to have an adverse effect on the environment (section 314(1)(a)).

- require a person to do something that is necessary in order to ensure compliance by that person with the RMA, or is necessary to avoid, remedy, or mitigate any actual or likely adverse effect on the environment caused by that person (section 314(1)(b)).

- require a person to remedy or mitigate any adverse effect on the environment caused by or on behalf of that person (section 314(1)(c)).

- require a person to pay money to or reimburse any other person for any actual and reasonable costs and expenses which that other person has incurred or is likely to incur in avoiding, remedying, or mitigating any adverse effect on the environment, where the person against whom the order is sought fails to comply with an order under any other paragraph of this subsection or an

abatement notice or any of that person's other obligations under the RMA (section 314(1)(d)).

- require a person to do something that is necessary in order to avoid, remedy, or mitigate any actual or likely adverse effect on the environment relating to any land of which the person is the owner or occupier (section 314(1)(da)).

266. An enforcement order may also require the restoration of any natural and physical resource to the state it was in before the adverse effect occurred, including the planting or replanting of any tree or other vegetation (section 314(4)).

267. Two strands of potential liability arise from contravention of an abatement notice, or an enforcement order made by the Environment Court, under the RMA. Most significantly, contravention of an enforcement order constitutes an offence (section 338(1)(b)). It is also an offence to contravene most abatement notices (section 338(1)(c)). In both cases, the penalty is imprisonment on conviction for a term not exceeding 2 years or a fine not exceeding $200,000, and, if the offence is a continuing one, to a further fine not exceeding $10,000 for every day or part of a day during which the offence continues (section 339(1)).

7.3. Accident Compensation and Personal Injury

268. Professor Stephen Todd prepared a comprehensive paper for the Royal Commission on Genetic Modification setting out existing forms of liability both under the Accident Insurance Act 1998 (the AIA) and at common law, and has applied existing principles of liability to scenarios involving personal injury or damage to property arising from activities involving GMOs.153 A summary of his paper follows.

269. There are three kinds of damage which may arise from a GMO: personal injury, property damage and financial loss.

270. Todd identifies a series of examples of the kinds of damage that may be caused by GMOs, similar to those listed above in section 3.3.

7.3.1. **Personal injury – the Accident Insurance Act 1998**

271. The first point of reference in determining the liability of any person for injury to another is the AIA as all questions of liability operate subject to the accident compensation scheme. A person whose claim for personal injury is covered by the AIA cannot pursue a cause of action at common law. The relevant categories of personal injury covered by the AIA are:

153 Stephen Todd "Liability issues involved, or likely to be involved now or in the future, in relation to the use, in New Zealand, of genetically modified organisms and products" www.gmcommission.govt.nz.

(a) Personal injury caused by an accident; or

(b) Personal injury caused by medical misadventure; or

(c) Personal injury caused by a work-related gradual process, disease or infection.

(d) (There are six other categories under the AIA which Todd does not regard as relevant to his discussion).

Personal injury

272. Under Section 29(1) of the AIA, "personal injury" means:

(a) The death of an insured; or

(b) Physical injuries suffered by an insured including, for example, a strain or a sprain; or

(c) (c) & (d) [certain forms of mental injury].

273. "Physical injuries" referred to at (b) above are understood to mean any condition involving harm to the body, including harm by sickness or disease, that is more than merely trifling or fleeting. Personal injury is covered for compensation under the AIA when it comes within one of the specified grounds listed above, being caused by an accident, caused by medical misadventure, or caused by a work related gradual process, disease or infection.

The first category - personal injury by accident

274. Under section 28(2) "accident" means:

(a) a specific event, or a series of events, that –

(i) involves the application of a force or resistance external to the human body; and

(ii) is not a gradual process;

(b) the inhalation or oral ingestion of any solid, liquid, gas or foreign object on a specific occasion. This kind of occurrence does not include the inhalation or ingestion of a virus, bacterium, protozoa or fungi unless that inhalation or ingestion is a result of a criminal act of a person other than the insured.

275. An injury caused by genetic modification would not qualify under (a) above, as there is no application of force or resistance external to the human body. However the ingestion of genetically modified food on a specific occasion, causing personal injury, would qualify under (b) above. Of note is that the ingestion causing personal injury must occur on a "specific occasion", which would exclude any cumulative harm over time. Action for cumulative harm could, however, be pursued at common law.

The second category - medical misadventure

276. Personal injury caused by medical misadventure means personal injury caused by medical error or medical mishap (section 35(1)). "Personal injury" in this context includes injury by disease or infection and any other form of bodily harm. Fitting the criteria for "accident" is not relevant here.

277. "Medical error" is where a registered health professional fails to observe a standard of care and skill reasonably to be expected in the circumstances (section 36(1)). Thus the focus is on the registered health professional's negligence or culpability, and not on the existence of a certain type of injury. A medical error involving gene modification or the administration of a genetically modified drug in the course of medical treatment by a registered medical professional would be covered by the AIA.

278. There are four elements to "medical mishap", which means:

An adverse consequence of treatment when -

(e) the treatment is properly given by or at the direction of a registered health professional; and

(f) the adverse consequence is suffered by the insured; and

(g) the adverse consequence is severe; and

(h) the likelihood of the adverse consequence occurring is rare.

279. "Severe" means dying or being hospitalised as an inpatient for more than 14 days, or suffering significant disability lasting more than 28 days. To be "rare" the probability of an adverse consequence must be that it would not occur in more than 1% of cases where that treatment is given. Todd notes that the accident compensation scheme is not intended to underwrite the success of medical treatment. Although the threshold for "medical mishap" is extremely high, Todd states that it seems likely that an adverse consequence of medical treatment involving genetic modification would qualify as "rare" and would be covered for compensation if the results were severe.

The third category - work-related disease

280. This category of harm would apply to personal injury suffered by a person who works in an area involving genetic modification, such as a practitioner or a researcher. The compensation scheme covers personal injury caused by a work-related gradual process, disease or infection in circumstances where a person performs an employment task or works in an environment that has a particular characteristic, this characteristic causes or contributes to the injury, and the risk of suffering the injury is significantly greater for persons performing that task or working in that environment than for other persons.

281. 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 AIA, then a private action for damages is possible. Todd notes that the main possibilities that would not receive cover under the AIA, that might be pursued under the common law, are personal injury caused by ingestion not amounting to an accident, or by viruses.

7.3.2. Personal Injury not Covered by the AIA

282. An action for negligence can be brought against any person whose negligence contributes in some way to the damage suffered by the plaintiff. There are five limbs to negligence.

283. First, a victim of personal injury must show that the defendant owed him or her a duty of care, which is established if it is determined that the defendant should reasonably have foreseen that his or her negligence might cause injury to the plaintiff. Second, the defendant must have breached that duty of care, which means that the defendant must have failed to meet the standard of care reasonably to be expected of a person in the defendant's position, holding the relevant skill and experience. Third, the plaintiff must have suffered personal injury. Fourth, the plaintiff must be able to link the defendant's breach of the duty of care with the injury suffered by the plaintiff. That is, there must be a causal link between the breach and the damage. Last, the personal injury or harm must be a reasonably proximate consequence of the breach, that is, it must have been proximate.

284. Todd notes that there are a number of difficulties associated with proving all of the above components of negligence. In establishing a duty of care the courts apply an objective test, such that the foresight must be that of a "reasonable person" in the defendant's position and the risk to be foreseen must be a "real risk". A reasonable person in the position of the defendant must be able to foresee something more than "far fetched" or "fanciful". Due to the general uncertainty surrounding genetic modification activities, fulfilling the requirement of a foreseeable risk is likely to pose some difficulty. Todd does however note that a small or remote risk can nonetheless be a "real risk".

285. If the existence of a foreseeable risk is established, and the defendant was negligent, a plaintiff must also be able to link the negligence with his or her harm. Again, due to the uncertainty surrounding genetic modification activities, this requirement could be especially hard to meet. However, Todd comments that the difficulty may in fact be no different to that which can arise in other tort actions, and also that identifying persons responsible for harm arising from genetic modification activities may be simplified by the fact that often genetically modified products are patented.

7.4. Common Law Grounds of Liability

286. The tendency is to resort to existing sources of liability as administratively and conceptually convenient. Nonetheless, the Commission's report also signals an opportunity to review and reconsider the strategic objectives and conceptual underpinnings of New Zealand risk assessment policies and liability issues in what is a novel arena – genetic modification. We advance such a discussion in sections 8 and 9 below. First, however, this paper turns to the existing state of New Zealand legal liability issues (outside of HSNO). In this sense, the situation in New Zealand is not unlike that in the United States. Congress has not acted on developing a comprehensive regulatory scheme addressing GMOs or biotechnology generally.[154]

7.4.1. Claims for Damage to Property

Negligence

287. The same principles of negligence that apply in claims for personal injury, apply in claims for damage to property. However, wherever possible a plaintiff is more likely to rely on a claim under the rule in *Rylands v Fletcher*, or nuisance. The rule in *Rylands v Fletcher* and nuisance are strict liability offences, and therefore they are easier to establish than a claim of negligence.

Nuisance

288. 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 open to the defendant, regardless of any steps the defendant may have taken to try and avoid the harm. Where the activity causes interference with the enjoyment of neighbouring land, without physically damaging it, the activity must also be "unreasonable". That is, it must exceed what an ordinary neighbour would regard as acceptable or could reasonably be expected to tolerate. The plaintiff must be a person with an interest in the land damaged, and the defendant must have possession or control of the land from which the nuisance emanates. Damage causing loss of profit is also recoverable.

289. Although both nuisance and negligence involve a "foreseeability of harm" test, the difference between nuisance and negligence is that nuisance is not concerned with the defendant's conduct but with fixing a threshold of unreasonable interference. Also, the foreseeability requirement will only exclude liability in cases where an activity thought to be harmless turns out to involve unforeseen risks of harm.

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154 A Bryan Endres, "GMO: Genetically Modified Organism or Gigantic Monetary Obligation? The Liability Schemes for GMO Damage in the United States and the European Union", 22 *Loy L A Int'l & Comp L Rev* 453, 481-482 (2000).

290. The *Watson* case mentioned above supplies some clues as to how this difficulty with foreseeability might arise. In that case, the risk of contamination through cross-pollination was considered to be "zero". Nonetheless, the Court of Appeal, although not called upon to consider any damage (none had occurred), appreciated that the damage would be "grave". Watson's counsel had argued:

> If cross-pollination occurs, it will have a devastating effect upon the applicant's business, reputation and livelihood. The Soil Association take an absolute stance with regard to accreditation. Not merely would the organic status of the applicant's present sweet corn crop be imperilled; so too would the rest of his farming enterprise.[155]

The Rule in Rylands v Fletcher

291. 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 the person who for his or her own purposes brings on to his or her land and collects and keeps there anything likely to do mischief if it escapes, must keep it in at his or her peril and, if he or she does not do so, he or she is answerable for all the damage which arises as a consequence of its escape. Like nuisance, liability under the rule is strict and it is irrelevant whether the defendant took preventative steps or tried to avoid a situation where the harmful thing could escape. The escape and consequent harm of the thing must have been foreseeable, but the manner or cause of escape need not have been.

292. The difference between nuisance and the rule in *Rylands v Fletcher* is the requirement under the rule that the defendant is making a "non natural" use of the land. The use must be a special use bringing with it increased danger to others, and not merely the ordinary use of the land or a use which is proper for the general benefit of the community. The justification for maintaining the rule separately from negligence is that activities imposing inherent risks should not be prevented altogether where they have some social utility, but the person responsible for the activity should pay for any escape and harm arising from the activity.

Application of Nuisance and Rylands v Fletcher to GMO Scenarios

293. First, liability is easier to establish if land has been physically damaged, as opposed to merely interfered with. "Physical damage" means a significant physical effect on property or a physical change, and where the property is living a physical change can include change to genetic structure (Todd cites a case involving the contamination of crops which were then fed to cattle, affecting their saleability).

294. If there is a one-off incident of actual escape and the rule in *Rylands v Fletcher* applies, a court must decide whether the genetic modification activity or the gene

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155 *R v Secretary of State for Environment and Ministry of Agriculture Fisheries and Food ex parte Watson* [1999] Env LR 310, 315.

technology in question is a non-natural use of the land. Did the activity create a special danger involving an inherent risk of harm?

295. If an action in nuisance or under the rule in *Rylands v Fletcher* exists the defendant could be held liable regardless of any care taken but, as with negligence, the harm suffered by any plaintiff must have been foreseeable.

7.4.2. Liability of Approving Agencies

296. ERMA is a public body set up by statute with powers to decide whether or not to approve applications involving GMOs. A question arises as to whether ERMA might be liable for negligence in giving or refusing an approval. A similar question arises as to whether the Ministry of Agriculture and Forestry (MAF), as the body responsible under the Biosecurity Act 1993 for approving facilities where GMO work is carried out, might be liable for negligent approval of the facilities.

Giving Approval

297. Todd notes that the case law relating to approving agencies is unclear and inconsistent but that recent cases show greater readiness on behalf of the courts to uphold "preventative" duties. The following factors can be taken from the cases which point towards the duty:

(iii) The defendant authority was in a position of control and was under a statutory obligation, or at least had specific power, to protect the plaintiff from the danger;

(iv) The defendant knew or ought to have known of the risk of harm to a specific, known plaintiff or a specific class including the plaintiff;

(v) The plaintiff was in a position of special vulnerability or dependence on the defendant. He or she could not reasonably have been expected to have safeguarded himself or herself from the danger;

(vi) On a policy overview there is no good reason for denying a duty. In particular, a duty of care can be seen as consistent with and complementary to the performance by the public body of its statutory functions.

298. Applying these factors, Todd states that it is likely that ERMA or a similar body would be held to owe a duty of care to persons who suffer physical injury or property damage caused by a GMO which had been approved for release or for experimentation. Similarly, a duty would be likely where a property owner complains of contamination caused by genetically modified plants replacing existing plants or having an adverse effect on the land.

299. However it is unlikely that a body such as ERMA could be liable in nuisance where it has not been negligent. ERMA or a similar body would not be "in possession or control" of the land from which any nuisance came, thus it would not fulfil one of the negligence requirements.

Refusing Approval

300. It is conceivable that an individual might complain that he or she has lost an opportunity to be cured of some existing illness if ERMA were to refuse an application for approval of research or field trails of a GMO. The AIA would not apply (there would have been no "accident" or "medical misadventure"), so an action in tort might be possible. However, establishing the components of negligence would be extremely difficult for a plaintiff in this context.

301. First, when faced with situations involving claims against public bodies for alleged negligence in making decisions in the performance of their statutory functions, the courts have tended to ask whether the decision of the public body is justiciable and, if it is, whether general policy considerations count against a duty of care. Although a decision may well be found to be justiciable, policy considerations would have a strong influence in pointing away from the existence of a duty of care.

302. Even if a duty of care could be established, proving that it had been breached would involve proving that the decision of the public body had been made negligently, that the risks had been over-estimated and that the benefits and advantages of giving approval should have outweighed any possible risks. It is highly likely that a court would be reluctant to replace the decision of the public body with its own in relation to these matters.

303. Further, even if negligence could be shown, a plaintiff would also have to establish that an *approval* for research or trialling would certainly have led to a treatment which would have been effective to avoid his or her harm.

304. Todd states that claims which seek to impugn the power of a public body to make a decision probably can succeed only if the elements of misfeasance in public office are made out. The criteria for this tort are completely different to those for negligence and require the actual knowledge and will of a public office holder to cause harm to the plaintiff or a class including the plaintiff.[156] According to Todd, claims against ERMA or similar bodies for alleged *negligence* in denying or withdrawing approval of an activity involving genetic research would be unlikely to succeed.

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156 The tort of misfeasance of public office requires the deliberate and dishonest abuse of public power by a public officer, by acting with the object of injuring the plaintiff or knowingly acting outside power with actual foresight that this would cause harm to the plaintiff or a class including the plaintiff.

7.4.3. Limitation of Actions

305. The law relating to limitation of actions is covered by the Limitation Act 1950. Assessing the law under the Limitation Act 1950, and recent developments in the relevant case law, Todd states that where harm caused by a GMO is latent the victim of the harm would still be able to bring a tort claim upon discovering the harm. In the case of personal injury any possible claim is not likely to be barred before the victim has a chance to assert it.

306. Where there is a claim for property damage or financial loss the situation is less certain. The ordinary six year limitation period applies but if the harm is latent, Todd comments that logic would suggest that the "discoverability" rule should apply.

307. Although the relevant case law is not entirely consistent, Todd tentatively comments that recent trends suggest that the discoverability rule will replace the date of damage principle, although this too is uncertain. Todd argues that the date of damage principle achieves no greater certainty than the discoverability rule, so the courts may be encouraged to favour the latter. He notes the recommendation of the Law Commission to introduce the discoverability rule across the board, with a ten year long stop principle from the date the cause of action accrued.

7.4.4. Insurance

308. Todd states that existing liability policies are likely to cover harm caused by GMOs as they generally have open wording, and provided that the relevant insured party has complied fully with the disclosure requirements of its insurance company, there is no reason (without specific exclusion) why GMO harm would not be insured for.

309. However, at present the understanding of any level of risk involved in activities involving GMOs is limited. If the insurance industry finds that it is unable to assess fully the risks and costs involved in genetic modification activities and to price insurance policies accordingly, it is likely to introduce changes excluding cover in relation to liability for harm caused by such activities. It is possible that insurance against at least some kinds of harm will become unobtainable.

310. However, Todd acknowledges the speculative nature of his observations and states that it may be that better knowledge and understanding will not show widespread risk of liability for parties involved in genetic modification activities.

8. The Case for Reform – Present Deficiencies

8.1. Introduction

311. The main deficiencies with relying upon the tortious action of negligence and nuisance and the rule in *Rylands v Fletcher* are as follows:

(a) First, each of the torts is dependent on individuals or classes of persons commencing and persevering with a suit against the person or persons allegedly responsible for the GMO source of damage (assuming, for the sake of argument that this causal connection can be proven). The costs and evidential difficulties (demonstrating causation) are substantial and the likelihood of, for example organic farmers persevering against Monsanto, is not great. The costs of such litigation are likely to deter complainants. Transaction costs will be high, due to determining which parties to involve and it what capacities and whether to proceed to litigation and to continue with it and also in the sense of any negotiations for final settlement or mediation.[157] Relying upon conventional common law forms of liability may encourage a perception amongst complainants or the public generally that actions against GMO users are ineffective.

(b) Second, 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 against GMO use or to defendants. These issues concern the problems of demonstrating causation, as outlined in section 3.3 above and the inherently probabilistic or statistical quality to the risks of damage resulting from GMOs. Specific statutory regimes would be of assistance in permitting a complainant or range of complaints to focus on a discrete series of matters to prove (evidential thresholds) and on specific defences, if any.

(c) Third, 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. Risk can be corralled even though there is no established claims history through linking insurable risk to a specific and transparent range of liability provisions. GMOs are controversial and, as a change technology, GM risks are more difficult to assess. Reform however should confront this ambiguity and uncertainty to establish transparent and explicit parameters for liability. Insurers are

157 Consider Coase's illustration of high transactions costs. Also refer to Richard Posner, *Economic Analysis of Law* (Little, Brown & Company, Boston, 1992), 62: "… if neither party has good alternatives to dealing with the other, transaction costs may be quite high. Negotiations to settle a lawsuit are an example. Because the plaintiff can settle only with the defendant, and the defendant only with the plaintiff, there is a range of prices within which each party will prefer settlement to the more costly alternative of litigation. Ascertaining this range may be costly, and the parties may consume much time and resources in bargaining within the range."; D Dewees, Duff and Trebilcock, *Exploring the Domain of Accident Law: Taking the Facts Seriously*, p. 266.

ambiguity averse. Through supplying clear provisions on liability, insurers will be in a better position to assess a developing history of experience with each type of GMO risk.

(d) Fourth, (and connected to point (c) above) specific liability provisions would more explicitly determine the extent of any socialisation of costs.

312. In the following subsections, we examine:

- Compensation and deterrence as objectives of liability provisions;
- Practical and conceptual problems with relying on the torts of negligence and nuisance and the rule in *Rylands v Fletcher*;
- Normative approaches to liability;
- The internalisation and socialisation of costs.

8.2. Compensation and Deterrence as Objectives

313. The objective of any legal liability provision is not merely to conform to a narrow pecuniary "deterrence objective" of costs and benefits in its (vulgar form) under conventional law and economics theory. Rather more substantial behavioural changes are required, particularly at the front-end of the approach to the risk assessment of GMO trialling and release. In this sense, the liability questions must operate in tandem with the front-end obligations of applicants for GMO trials and release under HSNO as much as possible, through encouraging rigorous risk assessment behaviours. Therefore, an enlarged conception of deterrence theory objective needs to be engaged; one that is tied to the risk assessment or appraisal processes to be observed on the part of entities engaged in GMO testing, trialling and release.[158] Applicants to ERMA are then encouraged to focus upon monitoring their compliance with conditions and forward risk assessment in a dynamic fashion (that is, on an ongoing basis through time).

314. Other than statute, the main sources of liability in the arena of GMOs and products are to be located in tort law. Two major objectives of tort law have been identified, specifically compensation and deterrence.[159] "Compensation goals" involve distributing the burden of injury costs and imposing costs on those with "deep pockets".[160] This goal ensures that the costs of injury or damage are not allocated to those who cannot bear it.

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158 Cf. Guido Calabresi, *The Costs of Accidents: A Legal and Economic Analysis* (Yale University Press, New Haven, 1970), 68-94 and discussions on the deterrence theory Dewees, D Duff, and M Trebilcock, *Exploring the Domain of Accident Law: Taking the Facts Seriously* (OUP, New York, 1996), 266-290 esp.; *vide*, cautions expressed regarding this literature in Peter Crane (ed.), *Atiyah's Accidents, Compensation and the Law* (Butterworths, London, 1999), 374-392.

159 Calabresi, "Concerning Cause and the Law of Torts: An Essay for Harry Kalvern, Jnr" 43 *U Chi L Rev* 69, 79 (1975).

160 *Ibid*, at 73-77.

315. Professor Calabresi, an influential legal theorist, distinguished between market deterrence and collective (or specific) deterrence.[161] Tort law attempts to deter costly injuries. Collective deterrence is distinguishable from market or general deterrence. Market or general deterrence encourages an internalisation of costs on the part of legal persons (including companies) and a resort to insurance. Needless to say, internalisation of costs of these types can also occur where collective deterrence is engaged, however, and it is important to note that a crucial distinction between collective deterrence and market deterrence involves the choice of behaviours of individuals. Market or general deterrence involves an individual actor determining or choosing whether or not to undertake injury or accident-prone activities through either shifting or not shifting to certain activities on the basis of accident costs as reflected in prices for the relevant activity.[162]

> There are two basic approaches to making these difficult "decisions for accidents", and our society has always used both, though not always to the same degree. The first, which I have termed the specific deterrence or collective approach, will be discussed later. At present it suffices to say that involves deciding collectively the degree to which we want any given activity, who should participate in it, and how we want it done. These decisions may or may not be made solely on the basis of the accident costs the activity causes. The collective decisions are enforced by penalties on those who violate them.
>
> The other approach, and the one I wish to discuss further, involves attempting instead to decide what the accident costs of activities are and letting the *market* determine the degree to which, and the ways in which, activities are desired given such costs. Similarly, it involves giving people freedom to choose whether they would rather engage in the activity and pay the costs of doing so, including accident costs, or, given the accident costs, engage in safer activities that might otherwise have seemed less desirable. I call this approach general, or market, deterrence.[163]

316. Collective deterrence accomplishes attempts to balance injury and safety costs through political, collective compromises. Arguably, collective deterrence is much more appropriate in the context of hazardous substance or new organisms litigation for two reasons:

(i) Market or general deterrence operates on the basis of individualistic (atomistic) choices to avoid accident costs, and there is no assurance that the individual's choice would be to avoid an accident even though there may be clear social claims and interests in favour of complete avoidance of such accidents, or as much avoidance as could be reasonably obtainable. This is due to the observation that market or general deterrence rests upon a calculus of costs *versus* benefits and, secondly, rests upon a specific legal conception of causation, specifically "but for"

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161 Calabresi, *The Cost of Accidents: A Legal and Economic Analysis* (Yale University Press, New Haven, 1970), 95.

162 Calabresi, *The Costs of Accidents: A Legal and Economic Analysis* (Yale University Press, New Haven, 1970), 73-75.

163 Calabresi, *The Costs of Accidents*, 68-69.

or *sine qua non* causation, in which a causal chain points to a particular event as the cause and hence attributes liability to the individual actor generating that event. Thus, market or general deterrence ordinarily utilises "but for" causation in practice, as it readily allows calculation of costs the cheapest cost avoider would incur.

(j) The difficulties involved in front-end risk assessment when embarking upon genetic modification research or trials indicates that where damage or injury might occur as a "delayed effect" or a "cumulative long-term effect", then it might be more appropriate to resort to probabilistic causation analysis rather than "but for" causation analysis which endeavours to readily identify an individual actor (whether a biological person or a corporate entity) legally responsible for the event that caused the resultant injury. The possible evidential problems involved with GMOs were canvassed briefly under the question of toxicity at in section 3.3.2 above. A sense of probabilistic evidence can be garnered from the following passage:

> It is easy here to be misled by the natural metaphor of single 'chain', which may lead us to think that the causal process consists of a series of single events each of which is dependent upon (would not have occurred without) its predecessor in the 'chain' and so is dependent upon the initiating action or event. In truth in any causal process we have at each phase not single events but complex sets of conditions, and among these conditions are some which are not only subsequent to, but independent of the initiating action or event.[164]

8.3. Problems with relying on torts and *Rylands v Fletcher*

317. As we have noted above, there are several relevant forms of strict liability that apply under common law, specifically where damage to land gives rise to liability in negligence, in nuisance or under the rule in *Rylands v Fletcher*. The difficulties with relying upon the strict liability forms of action under tort law is that neither has been noticeably effective to date in reducing environmental pollution. Crucially, for genetic modification cases, there is no evidence to date that the tort of nuisance or the rule in *Rylands v Fletcher* will be any more efficacious in ensuring a rigorous risk assessment process and the selection of conditions for genetic modification organism applications under HSNO.

318. 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

164 H L A Hart and J Honore, *Causation in Law* (1985) at 72.

costliness of the litigation is indeed worthwhile.[165] In the words of Coase, high transaction costs are involved in this scenario and the reasonably efficient resolution of the legal-environmental harm question is not necessarily accomplished at all.[166]

> Coase noted that if the law were clear and transaction costs were low, then polluters and pollutees could negotiate to an efficient level of pollution, regardless of the law's restrictions on pollution discharge. In these situations, the parties should be able to resolve the problem reasonably efficiently. Unfortunately, few environmental problems arise between a single polluter and a single victim. The overwhelming preponderance of pollution arise with multiple victims, often with multiple sources, and generally with great uncertainty relating to discharge, dispersion, and harm. Here the negotiations postulated by Coase will not take place, as he recognises in his high transactions costs case, so that careful examination of tort doctrine is important to determine whether an efficient solution will be reached.[167]

319. In this sense, the injurer in the case of genetically modified plants or crops, will not be readily deterred by the case by case possibility of dauntingly expensive pieces of litigation given that the possible range of plaintiffs is likely to be deterred from commencing any such action on the basis of conventional tort categories.

320. It is also possible, that the potential injurer will have endeavoured to minimise any risk through paying a reduced price for the land (whether in terms of purchase price or rent) with the discount intended to reflect the possibility that the operations commenced upon the land might need to be ceased or trimmed and moved elsewhere in the event of any tort action.

321. It appears desirable that specific regulatory mechanisms be designed to capture such situations in a way that ensures the most efficacious and efficient means of dealing with property damage that might result from genetically modified crops. In addition, any liability provisions ought to ensure a clear expectation that rigorous risk appraisals will occur prior to the commencement of any deliberate release of a GMO or any field testing.

322. *Causation* - Commentators recognise that proof of causation is a substantial obstacle to the resolution of tort claims based on injury from hazardous substances in general (including injuries resulting from toxic substances).[168] Thematically,

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165 In this context, refer to the useful discussion to be found in Richard Posner, *Economic Analysis of Law* (Little, Brown & Company, Boston, 1992), 63-64 (referring to the tort of nuisance).

166 Ronald Coase, "The Problem of Social Cost", 3 *J L & Econ* 1 (1960).

167 Dewees, Duff and Trebilcock, *Exploring the Domain of Accident Law: Taking the Facts Seriously*, p. 266.

168 See Pearce, "Encouraging Safety: The Limits of Tort Law and Government Regulation", 33 *Vand L Rev* 1281, 1298 (1980); Trauberman, "Statutory Reform of 'Toxic Torts': Relieving Legal, Scientific, and Economic Burdens on the Chemical Victim", 7 *Harv Envtl L Rev* 177,197 (1983); Brennan, "Causal Chains and Statistical Links: The Role of Scientific

the epidemic incidence of BSE within the United Kingdom constitutes a "rare event" where it has proved very difficult to identify the individual actor or a group of actors responsible for the resulting damage. Some transfers of genetic material by a certain pathway may satisfy causation tests – bees carrying pollen for instance. Some pathways, such as transmission through a virus or the jumping of a gene between species, would not necessarily satisfy the requirements of causation or reasonable foreseeability.

323. *Limitation of actions* – Likewise, causation is likely to be linked with complicated limitation of action issues under the Limitation Act 1950 (NZ). Environmental damage might very well be suffered by a complainant in circumstances where the damage was not reasonable ascertainable for a considerable period of time. Under section 4(1) of the Limitation Act a plaintiff bringing an action for personal injury or property damage must bring her action within a period of six years from the date on which the cause of action accrued. Under-deterrence of GMO producers is a definite risk where the limitation period dates from the time when the tortious act arose or occurred. As GMOs might cause latent harm that is not reasonably discoverable for some years, then the discoverability test for limitation is one that is favoured for accomplishing the "deterrence objective" in cases of environmental harm.[169] As Professor Stephen Todd has noted referring to the building construction case *Invercargill City Council v Hamlin*[170] it is not clear in cases of property damages which test for the limitation period will apply.

> The position where there is a claim for property damage or financial loss is more uncertain. Here the ordinary six year limitation period applies. If harm is latent, the question is whether the discoverability rule should again apply to determine when the cause of action accrued. The reasoning in building construction cases could apply in the present context. Where there is a latent defect in property, financial damage only happens when the defect is discovered, because only then is the value of the property affected. While it is unknown and, perhaps, unknowable, the owner can sell the property at full value and suffer no loss. […] But if the claim is seen as being for actual physical damage or change to crops and more than six years has elapsed from the date of that damage, the question is whether the discoverability rule in the personal injuries cases would be applied, so time would run from the date of the discovery of the physical damage or change and of its cause.[171]

324. The process of deterring potential injurers, however, is replete with difficulty. Theoretically and practically, persons who embark upon the approval process through ERMA ought to be assured that their legal liability will be rationally

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Uncertainty in Hazardous-substance Litigation" 73 *Cor L Rev* 469 (1988). *Report of the Royal Commission on Genetic Modification – Report and Recommendations*, I, p.319.

169 Dewees, Duff and Trebilcock, *Exploring the Domain of Accident Law: Taking the Facts Seriously*, p. 275.

170 [1994] 3 NZLR 513 (CA); [1996] 1 NZLR 513 (PC).

171 Todd, "Liability issues involved, or liability to be involved or in the future, in relation to the use, in New Zealand, of genetically modified organisms and products," www.gmcommission.govt.nz, pp. 19-20.

related to the statutorily structured risk assessment process that they undertook pursuant to HSNO. The design of any explicit liability provisions for inclusion in the HSNO regime must take such concerns into account. Nonetheless, the presence of these concerns is not in itself a rationale for evading the question of whether explicit administrative mechanisms need to be added to the HSNO regime since identical practical and theoretical difficulties would confront any defendant involved in a tortious liability suit on the basis of damage allegedly resulting from GMOs. Against this view, however, it is interesting to note that the Commission has perceived the difficulties associated with causation as justifying a continued resort to existing frameworks of tortious liability rather than designing novel and precise strategies to questions of liability.

> Devising a new form of liability will not, however, resolve the difficulty [of causation]; it is inherent in whatever kind of liability regime is adopted.[172]

325. Yet, crucially, the difficulties of causation remain and are likely to become more pressing if the public senses that the current forms of common law action are incapable of addressing novel areas of damage through GMO experimentation. Inertia is not the key even though it might seem convenient.

326. That said, the design of liability provisions has to be managed sensitively with a view to ensuring that the so-called "deterrence objective" does not actually result in undue deterrence of investment in GMO research within New Zealand. Any position of legal liability ought not to merely satisfy an adherence to an allocation of costs and benefits on a law and economics "deterrence objective" approach. There needs to be some linkage between the liability provision design and substantive and procedural fairness. In other words, liability (whether strict or otherwise) has to be rationally tied to the fault or blameworthiness of the defendant. On conventional law and economics analysis, the efficiency theory of the common law is that the common law is:

> [B]est (not perfectly) explained as a system for maximising the wealth of society. Statutory or constitutional as distinct from common law fields are less likely to promote efficiency, yet even they, as we shall see, are permeated by economic concerns and illuminated by economic analysis. Such analysis is also helpful in illuminating institutional or structural features of the legal system, including the role of precedent and the allocation of law enforcement responsibilities between private persons and public agencies.[173]

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172 *Report of the Royal Commission on Genetic Modification – Report and Recommendation*, I, p. 318.

173 Posner, *Economic Analysis of Law*, p. 23.

8.4. Normative Approach to Liability

327. Yet this law and economics approach is, in itself, insufficient to account for the difficulties associated with designing an explicit strategic liability regime.[174] Certain legal scholars have posited that regulatory design and tort law possess a normative role. Richard Epstein's central thesis is that ordinary language reflects certain moral ideals, one of which is that people are responsible for the harm they cause.[175] Something more than deterrence and compensation can be involved.

328. Indeed, censure of actions can also arise as a basis for tort liability on occasion (although awards of exemplary damages are more directly linked to censure) and certainly with the criminalisation of some acts of environmental damage.

329. The normative concerns of the criminal law are of some pertinence here, as it is concerned with notions of harm and the imputation of fault and liability for that harm or negative outcome. A degree of naming and shaming can arise with environmental damage and it remains important to strike a careful balance between consequences of liability for a defendant (levels of damages for example) and the defences that they can raise. While blameworthiness is a factor not often associated with strict liability regulatory offences - given the important conceptual distinction between culpability and liability – the imputation of liability must bear a rational relationship with the *ex ante* and *ex post facto* behaviours of the GMO user. By *ex ante* behaviours we would mean compliance with rigorous risk assessment procedures and ongoing duties to monitor new information; *ex post facto* behaviours would include efforts to mitigate damage.

330. A rational system of liability must not only be strategically oriented in terms of deterring undesired behaviours and compensating for losses but also sensitive to questions of substantive and procedural fairness. Absolute liability will not do and a reverse onus of proof in favour of plaintiffs claiming GMO users caused damage will undermine the "legitimacy" of a liability system as well as attract negative comment under the New Zealand Bill of Rights Act 1990 (NZ) and from the Ministry of Justice.

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174 It would be a vulgar rendition of Posner's view in *Economic Analysis of Law* if it was not acknowledged that Posner himself is sensitive to the areas of "justice" that cannot be explained through economic terms. See *ibid*, p. 27.

175 Epstein, "Defences and Subsequent Pleas in a System of Strict Liability", 3 *J Legal Stud* 165, 166 (1974).

9. Proposed New Liability Framework

331. This section sets out the proposed features of a new liability framework. It first addresses property or environmental damage and the nature of the strict liability test to accompany this. A further subsection considers personal injury and the place of GMOs under the cover provided by the accident compensation scheme.

9.1. Property Damage

9.1.1. Recommended Features

332. We recommend the following key features in respect of property damage:

(1) **Transparency and Precision -** Specific liability provisions addressing damage to property consequent upon the release of GMOs assists legal certainty regarding liability and transparency. The impact on potential defendants, complainants and third parties such as insurers (particularly in the area of cumulative or delayed inter-temporal harm) should be positive over time as experience and history is acquired with a specific working regime. The Commission's stance in favour of relying upon conventional common law sources of liability does not possess this practical advantage.

(2) **Strict liability provisions** - Definitions are critical here. "Damage", "adverse effect" or "harm" (depending upon the favoured term) must be precisely defined and exclude insignificant damage. Imprecision must be avoided where possible.[176] (This is discussed in more detail in the following subsection.)

(3) **Positive duty to Monitor –** We believe that the risk assessment process and liability provisions can be much more rationally connected and possess integrity if they are linked through an ongoing duty on the applicant to monitor GMO behaviour in field tests, containment, or under any release from containment.

(4) **Insurance -** Insurance should be a mandatory requirement of any GMO related approval given by ERMA. Accordingly, the risk assessment

176 Indeed, the United Kingdom refused to sign the Convention on Civil Liability for Damage resulting from Activities Dangerous to the Environment 1993 (also known as the Lugano Convention 1993) on the basis that the definition of environmental damage was intrinsically vague and potentially very wide, including as it does references to heritage and landscape. United Nations, Economic and Social Council, *Responses to the Questionnaire on the Convention on Civil Liability for Damage resulting from Activities Dangerous to the Environment (Lugano Convention)* (Geneva, 2001), p.7.

procedures undertaken at the front-end will be tied into the questions of liability and the polluter pays principle at the *ex post facto* liability end. Transitional provisions will address existing applications that ERMA has already approved. The preferred approach is not to set a predetermined quantum level restricting the liability, as discussed in section 4.2.

(5) **Mitigation of Liability -** Circumstances might occur where it would be inequitable to have the injurer paying full compensation for the damage caused. For example, a court could be permitted room to decide that part of the damage should be borne by the approval agency, ERMA. One appropriate case would be where the GMO user causing damage was explicitly permitted to use the GMOs in a fashion that led to the damage. That is, 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. This is a very difficult point, both conceptually and operationally and one that needs to be further debated.

(6) **Defences** – An absolute defence to liability (responsibility for the act causing harm or damage) would be *force majeure*, in the sense of natural disasters such as earthquakes, tsunamis, civil strife and so forth. Insurance contracts will tend to have an exception clause relating to any loss caused through such events. There will be minor defences regarding the degree of one's liability that would reduce an award for damages against the GMO user – specifically, mitigating circumstances as outlined above at (5). Examples would include third party contributions to damage on part of plaintiff or intervention by a third party.

333. None of these features are expected to be in conflict with any existing international obligations New Zealand has entered into. These considerations are further examined in Appendix 2.

9.1.2. Positive Duties to Monitor

334. **–** The HSNO legislation focuses on pre-identification of risk and potential damage. That orientation can be characterised as *ex ante* – principally directed towards the *ab initio* risk assessment and applications process for new organisms such as GMOs. However, GM is a "change technology" and our understanding of GMOs can vary over time, both from better information and from experience of their ability to mutate over time. Risk assessment may have been undertaken at point *t* – the time of the risk assessment and approval, but appreciation of the risks might have considerably altered at *t + 1* or *t +2*. This fluidity ought to be captured in the design of HSNO in a very clear manner.

335. Therefore, liability for "damage" should be connected to an ongoing positive duty on the part of the applicant seeking release to monitor and to report to the inspectorate already created under HSNO. In this way, both ERMA (as the

approval agency) and the applicant, are responding to the inter-temporal quality of any GMO technology. ERMA should not simply act as an approval agency but as a monitoring agency in this regard. The United Kingdom's Environmental Protection Act 1990 requires under section 109(4) that a person proposing to release GMOs:

> (a) shall take all reasonable steps to keep himself informed, by reference to the nature of the organisms and the extent and manner of the release (including any precautions to be taken against their causing damage to the environment), what risks there are of damage to the environment being caused as a result of their being released;
> (b) shall not release the organisms if it appears that, despite the precautions which can be taken, there is a risk of damage to the environment being caused as a result of their being released; and
> (c) subject to paragraph (b) above, shall use the best available techniques not entailing excessive cost for preventing damage to the environment being caused as a result of their being released;
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> and this subsection applies, with the necessary modifications, to a person proposing to market organisms as it applies to a person proposing to release organisms.

336. The existing provisions of HSNO therefore ought to be "boosted" to take an ongoing duty to monitor into account. Under HSNO, ERMA is already required to supervise inspection (section 99 of HSNO). Powers of entry and inspection are granted under section 103 of HSNO. Under section 104(1) of HSNO compliance orders can include an order requiring the cessation of "anything done or to be done" that:

> (i) Contravenes or is likely to contravene this Act, any regulations, or a control imposed by an approval under this Act; or
> (ii) Relates to any hazardous substance or new organism and is or is likely to be dangerous, to such an extent that it has or is likely to have an adverse effect on the health and safety of people or the environment; or
>
> (b) Requiring that person to do something that, in the opinion of the enforcement officer, is necessary to ensure that person complies with this Act, any regulations, controls imposed by an approval granted under this Act, or is necessary to avoid , remedy, or mitigate any actual or likely adverse effects on people or the environment resulting from any breach of any regulations or any controls imposed by an approval granted under this Act -
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> (i) Caused by or on behalf of the person; or
> (ii) Relating to any land of which the person is the owner or occupier.

9.2. Recommended Strict Liability Test

337. The following proposes an appropriate legal test for ascertaining liability for property damage caused by GMOs.

9.2.1. Principles

338. The principle of law applicable should be as follows:

> 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.

339. The principle of law above is wide but, it is submitted, not too wide. There are two potential defendants. A plaintiff can choose between them. There may be issues arising as to contribution and indemnity as between defendants but it is suggested those issues can be left to the courts. Liability attaches only to a person who sells or uses a GMO. It is a principle of strict liability, but there are defences.

340. The principle is also subject to a causation test which in practice is likely to prove quite limiting on the claim. The test is a cause-in-fact test or a substantial factor test. The plaintiff must demonstrate that the organism caused the harm. It will be necessary in most cases to have clear evidence that persuades a court on the balance of probabilities that the harm is attributable to use of the organism. That is, the evidence ought to establish that it was more likely than not that the harm was attributable to the use of the organism.

341. It should be noted that both sellers and users are liable and both will need to carry insurance.

342. The rule makes no mention of the approval process for GMOs, nor does it attach liability to the state agency carrying out the approval. It would probably be desirable to formally define by statute the potential liability of the Environmental Risk Management Authority.

343. The principle of law should be subject to a defence of contributory negligence on the part of the plaintiff. There is no inconsistency in applying the principles of contributory negligence to strict liability. It is done routinely in American law which imposes strict liability for dangerous and defective products – *Daley v General Motors Corp*.[177]

344. Estimating damages will give rise to difficulty in GMO cases. It is possible in some instances that the damage could be very substantial indeed. Plaintiffs will have to demonstrate tangible damage to their property. In many ways property damage is much easier to assess than personal injury damage. The recommendation in this report is that personal injury be dealt with under the

[177] 575 P. 2nd 1162 (Cal. 1978).

Accident Compensation Scheme in New Zealand and not be subject to determination under principles of civil liability in the courts.

345. Where property is damaged or destroyed, a plaintiff under the tort principles that are applied in New Zealand is entitled to restitution for the loss of its value to him. Usually this loss amounts to the cost of repair or replacement.[178] Where the damage is to a profit earning object a plaintiff may claim for loss of profits or for the cost of a substitute.

9.2.2. Pure Economic Loss, Physical Damage and Proximity

346. It is important to observe that the principle of law propounded above extends to pure economic loss. We acknowledge that there is a long line of authority in English and New Zealand law protecting purely economic interests against negligence liability.[179] However, we are of the view that economic loss of the kind where an organic farmer loses his or her accreditation with an organic farming industry representative body should be covered. It is exactly this form of loss (diminution in value of property rights) that has tended to emerge is some of the fact situations concerned with GMOs (for instance, the *Watson* case noted above). The courts should be trusted to apply the principles of proximity and reasonable foreseeability in this area. Australia affords a useful example in the guise of a recent decision of the High Court of Australia.

347. In Australia, the Gene Technology Act 2000 (Cth) does not provide a statutory basis for damages arising from GMO contamination. The common law is resorted to. However, the High Court of Australia has recently indicated that recovery for loss of certification and subsequent economic loss may be recoverable. In *Perre v Apand Pty Limited* one potato farm had been infected by bacterial wilt due to the negligence of Apand Pty Limited.[180] The Perre farm in South Australia had not been infected but because it was in the neighbourhood of the affected farm it lost its certification. Western Australian regulations prohibited the importation into that state of potatoes grown on land infected with that disease and also potatoes grown on a property within a radius of 20 kilometres from a known outbreak detected within the previous five years or, without regulatory approval, of potatoes processed with equipment or in premises with or within which potatoes grown within such an area had been handled. Potatoes could be sold more profitably from South Australia into Western Australia than in other available markets. The High Court of Australia held that the pure economic loss through loss of certification was enough for damages to be recovered. Hence, for organic farmers there is precedent that loss of certification could be relied upon evidentially for recovery of economic loss.

348. Hence, it will also be necessary for a plaintiff under the test propounded above to demonstrate that the use of the modified organism is a proximate cause of the

178 J G Fleming, *The Law of Torts* (8th Edition, 1992) 250.

179 See Generally J G Fleming, *The Law of Torts* (8th Edition, 1992), pp. 177-185.

180 *Perre & Ors v Apand Pty Ltd* (1999) 198 CLR 180 (HCA).

harm that he has suffered. This rule sometimes called "the remoteness of damage" has the effect of limiting the liability of defendants beyond a certain point.

349. The accepted rule in New Zealand law is that to be liable for the damage it must be reasonably foreseeable. There is a complicated set of legal tests and judicial authorities that lie behind this rule. The law is that the injury must be foreseeable as established by the Privy Council in 1961.[181] In a second case based on similar but not identical facts, the Privy Council held that a real risk was one which would occur to the mind of a reasonable man in the defendant's position and which he would not brush aside as far fetched.[182] The application of these remoteness of damage tests are not free from difficulty in the context of genetically modified organisms.

350. That is because some of the events are not likely to be easily foreseeable and may be freakish or abnormal. As the late Professor Fleming put it:

> the unforeseeable plaintiff may well serve as a useful break on any extravagant application of the principle that the extent of the foreseeable harm is irrelevant.[183]

351. Another way of looking at the issue is whether the consequences may fairly be regarded as within the risk created by the use of the GMO. This approach involves an analysis by the court of the scope of risk created by the defendant's conduct.

352. It is also clear under a remoteness of damage analysis that intervening causes will excuse a defendant.

353. Application of these tests can safely be left to the courts in New Zealand applying the well-established principles of tort law as they exist in New Zealand. But the legislature will need to establish the principle of strict liability so that the courts have adequate direction as to the liability principle they are to apply.

354. It may also be necessary to legislate for some aspects of the legal regime relating to GMOs so that it is clear that the statutory principle is the exclusive principle to be applied.

355. Further, it will be necessary to institute a regime of compulsory liability insurance by statute. This is necessary to ensure that where harm does occur a defendant that is sued under strict liability can satisfy any judgement. Otherwise the deterrent value of the liability required is lost; people without funds can behave irresponsibly with GMOs.

356. Given the fact that personal injury is dealt with under the accident compensation scheme and that liability for damage is limited in the manner set out

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181 *Overseas Tank Ships (UK) v Mortlocks Engineering Co* [1961] AC, p. 388.

182 *Overseas Tank Ships (UK) v Miller SS Co* [1967] 1 AC, p. 617.

183 J G Fleming, *The Law of Torts* (8th Edition, 1992), p. 214.

in the following subsection, the provision of insurance should not prove impractical or insurmountable under a legal regime of the type proposed here.

357. Special attention needs to be given to exemplary or punitive damages. These are damages that can be awarded by a court in addition to compensatory damage. The conduct must be extreme or outrageous. The accident compensation scheme for personal injury is in substitution for compensatory damages, but in some circumstances an action for punitive damages survives the Act. It is proposed that exemplary or punitive damages for egregiously wrong or reckless use of GMOs should be part of the New Zealand liability regime. It will act as a deterrent to irresponsible users and sellers.

9.2.3. Joint Tortfeasors

358. The question of joint tortfeasors also emerges, as it will be possible for a plaintiff to proceed against a seller and a user of a GMO. Joint tortfeasors are those who commit the same tort and are jointly and severally liable. "Joint liability arises where there is concurrence in the act or acts causing damage, concurrent liability where there is a coincidence of separate acts which by their conjoined effect cause damage."[184] Joint or concurrent tortfeasors will be liable for the loss in full. Under the Law Reform Act 1936, an unsatisfied judgement against one tortfeasor on a joint tortfeasor or concurrent tortfeasor basis will not bar recovery against the other tortfeasor or tortfeasors (section 17(1)(a) of the Law Reform Act 1936). There are possibilities for a tortfeasor to claim contribution from another tortfeasor "who is or would if sued in time have been liable in respect of the same damage."[185]

9.3. Liability for Personal Injury

359. There are three categories under the Accident Insurance Act 1998 that are relevant to GMOs:

- Personal injury caused by an accident;
- Personal injury caused by medical misadventure;
- Personal injury caused by work-related gradual process disease or infection.

360. The application of all of these definitions, both in the existing law and that contained in the Injury Prevention and Rehabilitation Bill (before Parliament at the time of writing) raises difficult analytical issues as to when a particular condition caused by a GMO will be covered by the scheme and when it will not.

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184 Todd *et al*, *The Law of Torts in New Zealand* (Brookers, 3rd ed., Wellington, 2001), p. 1143.

185 Section 17(1)(c) of the Law Reform Act 1936.

9.3.1. GMOs as a Distinct Category Under Accident Compensation

361. Rather than attempt to modify the existing tests in the accident compensation legislation to deal with GMO accidents that result in what might be generally called personal injury, it seems preferable to deal with the entire category and administer it under the Accident Compensation legislation. Otherwise some events that result from GMO may fall within the terms of the legislation and others outside. The distinction will be difficult and expensive to draw in practice. Further, it will lack any degree of social justice from the point of view of the injured person.

362. It would be possible to exclude all such conditions from the scheme on the basis that there are no levy payers who are contributing to the funding of the scheme by way of paying levies on the use of GMOs. In the absence of such a contribution, the costs of GMO damage will fall on other levy payers, who are not actually engaged in the activity that causes the harm.

363. The third option is to leave the law as it is. But that seems undesirable since the degree of uncertainty is high and the effect of GMO accidents on individuals, should they occur, could be severe.

364. Thus, while the total risk may not be very great, it can be argued that it would be prudent to guard against it in advance by deciding that the accident compensation scheme should cover all forms of personal incapacity that result from GMOs. In saying this, it is appreciated there will be substantial difficulties in individual cases in proving causation. But where causation can be established, coverage under the scheme should be provided for.

365. Thus, the appropriate policy appears to be to make a separate provision in the Injury Prevention and Rehabilitation Bill to deal with GMOs.

366. If this policy argument is accepted, a new definition of personal injury specific to GMOs is required. The policy would be that personal injury under the Act includes any incapacity that results from the release of GMOs. It needs to be made clear that whether the incapacity results from something in the nature of a personal injury or a disease is irrelevant if the instrument of its causation is a GMO.

9.3.2. Necessity for a Separate GMO Account

367. If this policy is adopted, it will also 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 for the purposes of the legislation those who hold consents or approvals for the release of GMOs in New Zealand.

368. This proposal is consonant with the policy embodied in the accident compensation legislation. While it may not be necessary to establish a separate

levy at this time, the Corporation does need to be empowered explicitly to compensate people who suffer from this activity and also to collect levies from those who generate the risks.

369. There are a number of other practical advantages in deciding to cover the possible personal incapacity resulting from the use of GMOs in New Zealand by the accident compensation legislation. The first is that it will give a sense of reassurance to people who are nervous about the use of these organisms as it is likely to be assumed that eventual liability will result in greater industry caution. It will also ensure that harm that results from their use will not be visited upon individuals with no hope of any relief.

370. A further advantage of including such personal injury under the accident compensation scheme is that it reduces the burden other insurers will need to shoulder when supporting applications to ERMA. In those countries where there is no accident compensation scheme - including the United States, the United Kingdom, Canada and Australia - the fashioning of liability rules for property damage is likely to be more difficult because of the absence of a separate regime for personal injury.

371. In the New Zealand context, a choice must be made whether to include GMO personal injury damage within the Accident Compensation Scheme or outside it. The arguments favouring including it seem overwhelming on social policy grounds.

10. A HSNO Reform Bill

372. This section draws together the principal recommendations from this report to frame (in outline) a draft reform Bill for discussion. These provisions would amend HSNO and become part of the HSNO regime. While the following relates specifically to GMOs, a number of the points – especially compulsory insurance cover - could well have general application under HSNO.

373. The definitions used in the provisions below are very broad and are intended to invite discussion and debate rather than to conclude matters.

> **Interpretation –** (1) In this Act, unless the context otherwise requires –
>
> "Person" includes the Crown, a corporation sole, and a body of persons (whether corporate or unincorporate):
>
> "Supplier of a genetically modified organism" means any person who –
>
> (i) Transfers the ownership or the possession of a genetically modified organism pursuant to a gift, contract of sale, exchange, lease, hire, or hire purchase to which that person is a party; or
>
> (ii) Licences or permits a person to distribute or to use a genetically modified organism or to exercise any rights, benefits or privileges in relation to a genetically modified organism; or
>
> (iii) Permits an agent, assignee or any other person to supply a genetically modified organism to any person: and
>
> (iv) Does not include the Authority:
>
> "Supply" means supply by way of any grant, provision or conferring of a genetically modified organism and includes any gift, sale, exchange, lease, hire, or hire purchase.
>
> **Liability for damage and loss –** (1) Any person who is a supplier of a genetically modified organism or uses any genetically modified organism in containment or release from containment or in any field test shall be liable for any physical harm, damage or economic loss to property caused by that genetically modified organism.
>
> (2) It is a defence to liability of the kind referred to in subsection (1) of this section, if the defendant proves that the harm, damage or economic loss was due to an event beyond the control of the defendant, including natural disaster, or sabotage.
>
> (3) Any monetary remedy awarded for any liability of the kind referred in subsection (1) of this section may be reduced if, in the opinion of the Court, the defendant took all reasonable steps in the circumstances to mitigate or remedy the effects of the harm, damage or economic loss after it occurred.
>
> **Joint Liability and Contribution –** (1) Subject to the following provisions of this section, any person liable in respect of any damage suffered by another person may recover contribution from any other person liable in respect of the same damage (whether jointly or otherwise).

(2) Any person shall be liable to make contribution by virtue of subsection (1) above notwithstanding that the person has ceased to be liable in respect of the damage in question since the time when the damage occurred, unless the person has ceased to be liable by virtue of the expiry of a period of limitation which extinguished the right on which the claim against the person in respect of the damage was based.

(3) A person shall be entitled to recover contribution by virtue of subsection (1) above notwithstanding that he or she has ceased to be liable in respect of the damage in question since the time the damage occurred, provided that he or she was so liable immediately before he or she made or was ordered or agreed to make the payment in respect of which the contribution is sought.

(4) A person who has made or agreed to make any payment in bona fide settlement or compromise of any claim made against him or her in respect of any damage (including a payment into court which has been accepted) shall be entitled to recover contribution in accordance with this section without regard to whether or not they were ever liable in respect of the damage, provided, however, that they would have been liable assuming that the factual basis of the claim against them could be established.

Concurrent liability – The Authority shall be concurrently liable for any damage, harm or economic loss under [section 2] where it failed to exercise reasonable care in approving the field test, containment or release from containment of the genetically modified organism.

The following are outlines of provisions that still require drafting. Rather than formalise these provisions, at this stage we have opted for outlining them for discussion:

Compulsory insurance –

- Each application to ERMA shall be supported by a letter from an insurer affirming that it is willing to provide cover in line with ERMA's minimum conditions for the application in question
- ERMA shall develop a schedule of minimum insurance conditions for each type of application including: the requirement that coverage is for unlimited liability and is reinsured with an approved reinsurer
- An application approved by ERMA shall not become effective until insurance cover has been obtained and proof of this lodged with ERMA

Performance Bond -

- Each party whose application to ERMA has been approved shall provide to ERMA a performance bond
- The bond may be in the form of a guarantee from the applicant's banker or may be provided in cash or other similar liquid securities
- The value of the bond shall be set by ERMA, but shall not be less than the excess required to make operative the insurance cover required for the programme approved by ERMA.
- ERMA shall devise guidelines for its setting of bonds and these shall specify that bonds will be set in accordance with different classes of risk.

They shall also ensure that the scale of bonds incentivise safety-oriented performance.

Release Permits -

- Each application to ERMA for release shall specify a programme for distribution of the GMO
- Each successful applicant for release or use of a GMO shall receive a permit for undertaking those activities specified in the programme and bond levels shall be set in accordance with the programme
- Application may be made to vary the programme, and the bond level accordingly

Monitoring -

- Applicants shall monitor any GMO release and shall provide to ERMA in a timely manner, any information in its possession relevant to understanding the risks pertaining to the GMO in question, that has not already been provided to EMRA
- ERMA shall continually monitor and assess the risks of GMOs permitted for release

Appendix 1: HSNO Act Provisions

A1.1 Effectiveness of HSNO in Allocating Liability

1. While HSNO creates its own unique set of offences which relate to non-compliance with its procedures for obtaining approval to import, release or develop new organisms, it also provides an "escape" for potential defendants who have complied fully with the procedures but have nonetheless caused harm to the people or to environment.

374. It may be that manufacturers or developers of GMOs undergo the application process in strict accordance with HSNO's regime, comply fully with all controls imposed upon them, and yet an unforeseeable mechanical failure or natural disaster causes a breach of one of the section 109 strict liability events to occur (such as a release into the environment of a GMO where approval only for laboratory testing has been obtained). The potential defendant is protected under section 117(2)(b). Liability for any resultant harm from the release of the GMO contrary to the ERMA approval would have to be pursued and established at common law.

A1.2 Purpose of HSNO

375. The purpose of HSNO is "to protect the environment, and the health and safety of people and communities, by preventing or managing the adverse effects of hazardous substances and new organisms". The definition of a new organism specifically includes a genetically modified organism or GMO (section 2A(1)(d)).[186] HSNO establishes a management regime for the potential effects of new organisms, the core of which is the establishment of mandatory criteria and procedures for applications to manufacture, import or release new organisms.

A1.3 Approval regime

376. HSNO prohibits the importation, development, fields testing, or release of any new organism except in accordance with an approval issued under its auspices (section 25). The types of approval relevant to new organisms are, under section 27:

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186 "Genetically modified organism" is defined under section 2 of HSNO and means "…any organism in which any of the genes or other genetic material –(a) have been modified by *in vitro* techniques; or (b) re inherited or otherwise derived, through any number of replications, from any genes or other genetic material which has been modified by *in vitro* techniques. "Organism" is also defined as follows: (a) does not include a human being or a genetic structure derived from a human being; (b) includes a micro-organism; (c) includes a genetic structure, other than a genetic structure derived from a human being, that is capable of replicating itself, whether that structure comprises all or only part of an entity, and whether it comprises all or only part of the total genetic structure of an entity; (d) includes an entity (other than a human being) declared to be an organism for the purposes of the Biosecurity Act 1993; (e) includes a reproductive cell or development stage of an organism.

(a) Approval to import for release or release from containment any new organism;

(b) Approval to import any new organism into containment, field test any new organism in containment, or develop any new organism in containment;

(c) Approval to import any new organism for release in an emergency, or release any new organism from containment in an emergency.

377. The body responsible for processing applications for the requisite approvals is the Environment Risk Management Authority (ERMA, also referred to as "the Authority" within HSNO itself), established under section 14 of HSNO.[187]

A2.4 Offences under HSNO

378. Part VII of HSNO sets out the provisions relating to inspection, compliance and enforcement of the Act. Section 109 lists the offences created by the Act. In essence, anyone who does not comply with the requirements for approvals to undergo certain activity relating to hazardous substances and new organisms in accordance with the Act commits an offence. The relevant parts of section 109 for our purposes are set out below:

> (1) Every person commits an offence against this Act who –
> …
> (b) Develops or field tests a new organism in contravention of this Act; or
> (c) Knowingly imports or releases a new organism in contravention of this Act; or
> (d) Knowingly, recklessly, or negligently:
> (i) Manufactures, imports, develops, uses, or disposes of any hazardous substance or new organism where any approval is suspended in accordance with section 64 of this Act;
> (ii) Possesses or disposes of any hazardous substance or new organism imported, manufactured, developed, or released in contravention of this Act; or
> (e) Fails to comply with -
> (i) Any controls imposed by any approval granted under this Act; or
> (ii) Any controls specified in any regulations; or
> (iii) Any requirement to obtain a test certificate specified in any regulations; or
> (f) Fails to comply with any compliance order served under section 107 of this Act; or
> ….
> (i) Being a manufacturer, developer, or importer of any hazardous substance or new organism knowingly fails to report any significant new information of any diverse effect of that hazardous substance or new organism;
> ….

[187] ERMA is a body corporate with perpetual succession and has all the rights, powers, and privileges, and may incur all the liabilities of a natural person of full age and capacity.

379. Different penalties apply depending on the perceived gravity of each offence. The penalties are set out at section 114, and range from imprisonment for a term not exceeding three months or a fine not exceeding $500,000, to no imprisonment but a fine not exceeding $5,000. Where any person is convicted of an offence against section 109, the Court has the discretion to replace or add to any term of imprisonment or fine, the revocation of any transferable permit.

380. The Court also has the discretion to order the destruction of any new organism, and to order a person to mitigate or remedy any adverse effects on people or the environment caused by that person or relating to any land of which that person is the owner or occupier, or to pay the costs of doing so. The fact that this discretion is specifically provided for indicates that the legislators at least contemplated that breaches of the approval regime could result in harm to people or the environment. The discretionary power of the Court is a mechanism by which defendants who cause adverse effects to people or the environment can be made liable for it by being ordered to remedy or mitigate the harm.

381. However, it is not the creation of the adverse effects itself which is an offence under HSNO, but the breach of the statutory approval regime. Thus a potential defendant who has caused harm, but has nonetheless complied with the letter of the law in HSNO, has a defence.

382. It is also worth noting section 109(1)(i), which relates to the provisions in HSNO requiring applicants to provide ERMA with all relevant information pertaining to a new organism. Section 109(1)(i) makes it an offence for manufacturers, developers or importers of new organisms (and hazardous substances) to knowingly fail to report any significant new information of any adverse effect of a new organism (or hazardous substance). Presumably the provision applies to any such persons who have sought and received the requisite approvals under the HSNO regime, so that in effect there is a positive duty on those persons to monitor and report on the new organisms in an ongoing manner. Other than this, ERMA is preoccupied with anticipating and assessing adverse effects *in futuro*. There is no clear liability regime for damage to the environment *per se*.

383. The sections of HSNO relating to the importation, release or development in containment of new organisms, with which people must comply in order not to commit an offence under HSNO, are set out.

384. Briefly, sections 34 to 38 of HSNO set out the assessment process of new organisms for importation or release. Sections 39 to 45 set out the process for containment approvals of new organisms. Sections 46 to 49 provide for the use of both hazardous substances and new organisms in emergencies (defined in section 46).

A2.5 Approvals for importation or release of new organisms

385. Section 34 provides that every person intending to import for release or to release from containment any new organism must first apply to ERMA for approval. Applications must be in the form approved by ERMA, and must include information prescribed by ERMA. The information required includes all the possible adverse effects of the organism on the environment (section 34(2)(e)).

386. Section 35 provides for the rapid assessment of the adverse effects of importing a new organism or of developing a new organism. Section 35 sets out:

> (1) Where the Authority receives an application under section 34 of this Act to import any organism **that is not a genetically modified organism** for release, the Authority may make a rapid assessment of the adverse effects of importing that organism in accordance with subsections (2) and (3) of this section. [Emphasis added]

387. If certain criteria are met under section 35(2), ERMA may approve the application without controls.

388. Section 19 empowers ERMA to delegate to any person, on such terms and conditions as it thinks fit, the power to conduct a rapid assessment under section 35 (and section 42, see below). Although ERMA can delegate all rapid assessments to other agencies, in practice the only decisions that it delegates are applications to develop GMOs in containment.[188] Such applications generally relate to new micro-organisms developed in test tubes for research. The institutions to which ERMA delegates the rapid assessment powers are normally universities and Crown research institutes. Decisions made by delegated institutions are treated in all respects as though they were decisions made by ERMA, and delegation does not prevent the performance or exercise of any function, power or duty by ERMA.

389. Section 36 sets out minimum standards that must be reached in order for ERMA not to decline any application. ERMA shall decline an application if the new organism is likely to:

> (a) Cause any significant displacement of any native species within its natural habitat; or
> (b) Cause any significant deterioration of natural habitats; or
> (c) Cause any significant adverse effects on human health and safety; or
> (d) Cause any significant adverse effect to New Zealand's inherent genetic diversity; or
> (e) Cause disease, be parasitic, or become a vector for human, animal or plant disease, unless the purpose of that importation or release is to import or release an organism to cause disease, be a parasite, or a vector for disease.

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188 Helen Atkin "The Legal Aspects of Genetic Modification" (August 2000) www.gmcommission.govt.nz, p. 6.

390. Of course, the obligation of ERMA to decline any application that does not meet the minimum standards is limited by the information known to the applicant and passed on to ERMA. However, ERMA also has the discretion to decline an application due to any insufficiency in the information provided (see below, section 38).

391. Under section 37, additional matters to which ERMA must have regard when making a decision under section 38 (determining applications to import or release new organisms), are:

> (a) The ability of the organism to establish an undesirable self-sustaining population; and
>
> (b) The ease with which the organism could be eradicated if it established an undesirable self-sustaining population.

392. Again, this provision is inherently restricted by the extent to which such information is known by the applicant, but ERMA's discretionary power under section 38 still allows it to make a judgment as to the sufficiency of the information provided to it and to act accordingly.

393. Under section 38, if an application made under section 34 has not been granted in accordance with the rapid assessment provisions of section 35, ERMA has the discretion to approve an application if the relevant organism meets the minimum standards set out in section 36, and if after taking into account section 37 and all the effects of the organism and of any inseparable organism the positive effects of the organism outweigh the adverse effects.

394. Conversely, ERMA has the discretion to decline an application if the organism fails to meet the minimum standards or if, after taking into account section 37 and all of the effects of the organism and of any inseparable organism, the adverse effects of the organism outweigh the positive effects. It also has the discretion to decline an application if insufficient information is available to enable it to assess properly the adverse effects of the organism.

395. Section 38(2) provides that any approval to import an organism for release, or to release an organism from containment, shall be granted without controls.[189]

A2.6 Containment approvals for new organisms

396. Turning to the provisions for applications relating to the containment of new organisms, under section 39 ERMA may approve the importation, development, or field testing of any new organism into containment for any of a number of

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189 "Controls" is defined under section 2 of HSNO and means "any obligations or restrictions imposed on any hazardous substance or new organism, or on any person in relation to any hazardous substance or new organism, by this or any other Act or any regulations, rules, codes, or other documents made in accordance with the provisions of this or any other Act for the purposes of controlling the adverse effects of that substance or organism on people or the environment".

listed purposes. These include (but are not limited to) the development of any genetically modified organism, field testing any new organism, maintaining new organisms in containment to produce antigens, biopesticides, biopharmaceuticals, enzymes, hormones, or vaccines for release or maintaining the organisms for diagnostic purposes, and other such purposes as ERMA thinks fit. Declining an application under section 38 shall not prevent ERMA from approving an application relating to the same new organism under section 39.

397. Section 40 requires every person intending to import into containment any new organism, or to develop any new organism in containment, or to field test any new organism in containment, to apply to ERMA for approval first. Again, applications must be in the form approved by ERMA, and every application must be accompanied by certain specified information.

398. For the purpose of assessing adverse effects of developing genetically modified organisms, section 41 provides that:

> The Governor-General may, from time to time, by Order in Council, make regulations–
>
> (a) Specifying the procedures and methods for assessing the probability that an adverse effect will occur from genetic modification of an organism;
>
> (b) Specifying the probability that adverse effects will occur from specified development procedures;
>
> (c) Specifying the circumstances in which genetic modification of an organism is a low risk genetic modification.

399. Regulations which have been made pursuant to section 41 are the Hazardous Substances and New Organisms (Low Risk Genetic Modification) Regulations 1998.[190]

400. Section 42 sets out:

> (1) Where the Authority receives an application under section 40 of this Act to develop a genetically modified organism in containment, the Authority may make a rapid assessment of the adverse effects of developing that organism.

401. Under section 42(2), if ERMA is satisfied that any such development meets the criteria for low-risk genetic modification specified in regulations made under section 41, it may approve the application and impose such controls providing for each of the matters specified in the Third Schedule of HSNO as it thinks fit. Again, the delegation power of ERMA contained in section 19 applies to this section.

402. Sections 43 and 44 set out additional matters to be considered when applications are made for developing new organisms in containment, and for

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[190] See (SR 1998/216), which specifies the circumstances in which genetic modification of an organism is "low risk" genetic modification.

applications for importing and field testing new organisms in containment respectively. Under section 45 ERMA has the discretion to either approve or decline an application made under section 40, and any approval under this section must include controls that provide for each of the applicable matters specified in the Third Schedule. It may also include controls that provide for any other matters in order to give effect to the purpose of the Act (section 45(2)).

A2.7 Procedures for Assessment

403. The procedures to be used by ERMA in assessing applications under HSNO are set out from sections 52 to 67A. These sections relate to the provision of information to ERMA, public notification requirements, receiving submissions, time limits and waivers, the obligation to hold a hearing and provisions relating to hearings, grounds for reassessment and provisions relating to reassessment, and requirements for the disposing of substances or new organisms which do not receive the requisite approval.

404. In particular, section 52 empowers ERMA to require an applicant to provide any further relevant information that ERMA considers the applicant able to provide. Under section 58 ERMA may commission a report or seek advice from any person on any matter raised in relation to an application. It may also obtain all existing relevant information on the organism which is the subject of the application, from any source.

405. The Minister for the Environment has certain powers over applications which have significant economic, environmental, international, or health effects or significant effects in any area in which ERMA lacks sufficient knowledge or experience.

A2.8 Strict Liability and Defences

406. The offences under section 109(1)(a), (b), (e), (f) and (g) are strict liability offences. That is, it is not necessary to prove that the defendant intended to commit the offence (section 117). However, a defendant charged with any of the above strict liability offences has a defence if he or she can prove that his or her actions were necessary for the purpose of saving or protecting life or health, or preventing serious damage to property, or avoiding actual or likely adverse effects on the environment (section 117(2)(a)). In addition, the conduct of the defendant must have been reasonable in the circumstances, and the defendant must have taken such steps as were reasonable in all circumstances to mitigate or remedy the effects of the action or event after it occurred.

407. It is also a defence to any of the strict liability offences if the defendant's actions were due to an event beyond the control of the defendant, such as a natural disaster, a mechanical failure, or sabotage (section 117(2)(b)). The action or event must not have been reasonably foreseeable and the defendant must not have been able to provide against it, and he or she must have taken such steps as were

reasonable in all the circumstances to mitigate or remedy the effects of the action or event after it occurred.

408. A further defence is that the actions which constituted the offence were within the defendant's control, but the defendant had taken all reasonable steps to prevent them and had in all the circumstances taken such reasonable steps as to mitigate or remedy the effects of the action or event after it occurred (section 117(2)(a)).

409. A further defence exists where a defendant charged under section 109(1)(e)(ii) or (iii) of HSNO complied with any code of practice provided under section 79 of HSNO, as a method of achieving the controls that it is alleged that the defendant failed to comply with (section 117(3)(a)). Also a defendant who holds a current test certificate issued in accordance with section 82 of HSNO, certifying that the controls that it is alleged that the defendant failed to comply with had been met, has a defence. The defendant must have had no reason to believe that the code of practice or the goods covered by the test certificate did not meet the relevant controls.

410. It is as a result of these defence provisions that a creator of harm to people or the environment through new organism-related activities, may possibly not be held liable for that harm pursuant to HSNO.

A2.9 Employers, principals and directors

411. Under section 115, employers are liable for any offence committed by any of their employees, whether or not the events took place with the employer's knowledge or approval. However, a principal is not liable for an offence committed by their agent unless the offence is committed with the principal's express or implied authority. Employers do have certain defences available to them where an employee has committed an offence against HSNO. It is a defence, for the employer to prove, that he or she did not know nor could reasonably be expected to have known that the offence was to be or was being committed, or he or she took such steps as were reasonably practicable to prevent the commission of the offence (section 115(3)). He or she must also have taken such steps as were reasonable in all the circumstances to remedy any effects of the act or omission giving rise to the offence.

412. Section 116 addresses the liability of directors and officers of bodies corporate. Where a body corporate is convicted of an offence under HSNO, every director and every person concerned in the management of the body corporate is guilty of the like offence it if it proved that the offence took place with his or her authority, permission or consent and that he or she knew or could reasonably be expected to have known that the offence was to be or was being committed and failed to take all reasonable steps to prevent or stop it.

A2.10 Liability of ERMA under the statutory regime

413. HSNO is silent as to any liability or ERMA, as a body corporate, in respect of any claimed damage or harm arising from the approval or decline of an application under the Act. ERMA could only be pursued under the common law. The First Schedule of HSNO does provide, at clause 33, that "no member or employee of the Authority shall be personally liable for any liability of the Authority, or for any act done or omitted by the Authority, or by the chief executive or any other employee of the Authority in good faith in pursuance or intended pursuance of the functions or powers of the Authority or of the chief executive."

Appendix 2

Relevant International Law and Conventions

414. There are a range of important international law obligations that relate to GMOs and a variety of international environmental law instruments that potentially have application, along with provisions of the World Trade Organisation (WTO) Treaties. This section briefly reviews those obligations and instruments.

A2.1 The precautionary principle

415. New Zealand is a party to the *Rio Declaration on Environment and Development* (1992) and Principle 15 sets out the following precautionary principle obligations:

> In order to protect the environment, the precautionary approach shall be widely applied by States according to their capability. Where there are threats of serious or irreversible damage, lack of all scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.

416. The precautionary principle resulted from recognition that scientific certainty often arrives too late to design effective legal and policy responses for the prevention of potential environmental threats. Almost all environmental issues involve conflicts analysis of scientific technical and economic factors. There is no such thing as perfect information available when legislators are asked to make decisions about whether to respond to a particular threat.

417. As one American text puts it:

> In essence, the precautionary principle switches the burden of scientific proof necessary for triggering policy responses from those who support prohibiting or reducing a potentially offending activity to those who want to continue the activity. Such a shift in the burden of proof could shorten the time period between when a potential threat to the environment is identified and when a legal response can be developed. The precautionary principle is one of the most important principles for anticipating and avoiding environmental damage before it occurs and thus it can lower the overall costs of mitigating or adapting to environmental damage.[191]

418. Although the declaration itself is not a binding norm of international law, there are arguments that the precautionary principle or something like it have become of customary international law and States are under an obligation to follow it.[192]

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191 David Hunter, James Salzman, Durwood Zaelke, *International Environmental Law and Policy* (1998), p. 360.

192 Edith Brown Weiss, *In Fairness to Future Generations: International Law, Common Patrimony and Intergenerational Equity* (1996), pp. 37-39.

Such a position requires proof of State practice, coupled with a showing that States are operating under a legal obligation to follow that practice, such arguments are made in the international literature.

419. The prodigious quantity of international treaties that have been negotiated since the Second World War is clear proof of the fact that no one nation State can handle the problems of trans-boundary pollution. It is truly an international problem, and many aspects of it require international solutions.

420. Such may turn out to be the case in regard to genetically modified organisms, but at this juncture no definitive judgements can be made.

421. In the absence of any clear international obligations upon New Zealand, the New Zealand domestic law-makers need to adopt a prudent approach to the enactment of provisions and ensure that the law that they enact is likely to be compatible with the international norms such as they are now and as they are likely to develop. Certainly the precautionary principle is one that will figure prominently in any such international negotiations and needs to be borne in mind in formulating domestic law on the subject.

422. In *Bleakley v Environmental Risk Management Authority*, the High Court did not accept submissions of the appellants that section 7 of HSNO introduced the "precautionary principle" to New Zealand, partly as a result of the Court's reading of the parliamentary debates prior to HSNO's enactment and partly because of what was considered to be the deliberate selection of the phrase "precautionary approach" in section 7 rather than "precautionary principle".[193] Hence, HSNO, the major source of domestic law in New Zealand on GMOs, can not be construed as a ready endorsement of the "precautionary principle". The front-end risk assessment orientation of HSNO is borne out in the Court's analysis on this point. As argued in preceding sections, the practical need for clear *ex post* liability provisions to complement this orientation appears necessary:

> I do not gain assistance from the suggested importation of the (somewhat uncertain) international concept of a "precautionary principle" whether such is expressed in terms of the Rio Declaration or otherwise. Hansard references cited tend to prove Parliament deliberately avoided that concept, even to the point of adopting the word "approach" rather than "principle". The section should be construed in its own language and in light of s4 purposes, one of which is declared to be "preventing or managing the adverse effects of … new organisms".
>
> I accept that there is, in the abstract, a conceptual difference between "risks" and "effects". The *risk* of something happening is different from the *effect* of its happening. The risk of a stored nuclear device exploding may be minimal. The effects of its doing so, if that minimal risk eventuates, will be catastrophic.

193 *Bleakley v Environmental Risk Management Authority* [2001] 3 NZLR 213 (HC) at 250; paras. [160]-[164] per McGechan J.

> However, we are reading a statute, not engaging in philosophy. When there is a reference, as in this statute, to "managing effects" the position becomes more obscure. Whatever the purity of concepts, it is possible within the ordinary use of language to say one can "manage" adverse effects inter alia by preventing those effects. […]
>
> In that light, I construe s7 reference to "managing adverse effects" as including management by reduction of risk such effects will ever arise. […][194]

423. The EU has adopted a relatively favourable outlook towards the precautionary principle, not merely as a basis for risk assessment but also as a basis for thinking about liability issues.[195] In Directive 2001/18/EC at Article 4(1) (underneath the heading of "general obligations") the:

> Member States shall, in accordance with the precautionary principle, ensure that all appropriate measures are taken to avoid adverse effects on human health and the environment which might arise from the deliberate release or the placing on the market of GMOs. GMOs may only be deliberately released or placed on the market in conformity with part B or part C respectively.

424. The emphasis on *ex ante* avoidance of adverse effects through risk assessment procedures is laudable. However, we are of the view that such an approach can be rationally assisted through proportionate liability provisions aimed at capturing *ex post* harmful consequences of adverse effects.

A2.2 Biodiversity

425. There is evidence discussed earlier in this paper that GMOs also have a potential adverse effects upon biodiversity. Biodiversity is an important international and environmental value legally protected by the Convention on Biological Diversity, concluded at Rio de Janeiro 5 June 1992.

426. New Zealand has ratified this Convention and is bound by it. The prime object of the Convention is the conservation of biological diversity, the sustainable use of its components of the fair and equitable sharing of the benefits arising out of the utilisation of genetic resources "including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over the resources and to technologies, and by appropriate funding" – Article 1.

427. The Convention does deal with biotechnology, which is devised as meaning "any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use." The prime principle of the treaty as stated in Article 3:

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194 *Ibid*, 50.

195 There are still differences in interpretation however. The operational means of accomplishing the precautionary principle are capable of much variation.

> States have, in accordance with the Charter of the United Nations and the principles of international law, the sovereign right to exploit their own resources pursuant to their own environmental policies, and the responsibility to ensure that the activities within their jurisdiction or control do not cause damage to the environment of other states or varies beyond the limits of national jurisdiction.

428. There are important conservation measures embodied in the Treaty. There is an obligation to "adopt measures relating to the use of biological resources to avoid or minimise adverse impacts on biological diversity" – Article 10.

429. There are obligations to carry out environmental impact assessments of projects that are likely to have significant adverse effects on biological diversity, and provisions concerning the handling of biotechnology and distribution of it.

430. The Convention also requires the parties to consider the need for "a protocol setting out appropriate procedures, including, in particular, advance informed agreement, in the field of safe transfer, handling and use of any living modified organism resulting from biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity" – Article 19.

431. Since the Convention also establishes a Conference of the Parties this would appear to be an appropriate international body to deal with the international problems of coordination and the formulation of rules of international law relating to genetically modified organisms.

A2.3 WTO

432. The WTO treaties, particularly the General Agreement on Tariffs and Trade, impose many obligations on nations that are parties to them including New Zealand. There are a number of unresolved issues here as well. It can be argued that GMOs should be entitled to enter international trade and that there are very few restrictions that receiving states can place upon the trading of such things as seeds and other organisms that may have been genetically modified, such as fruit and food.

433. The Agreement on Technical Barriers to Trade concluded at Marrakesh on 15 April 1994, which has entered into force and by which New Zealand is bound, was part of the Uruguay Round of Trade Agreements. All products, including agricultural products, are the subject of that Agreement.

434. There are serious restrictions on the technical regulations and standards that governments may impose. For example, paragraph 2.2 of that Agreement provides as follows:

> 2.2 Members shall ensure that technical regulations are not prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade. For this purpose, technical

> regulations shall not be more trade-restrictive than necessary to fulfil a legitimate objective, taking account of the risks non-fulfilment would create. Such legitimate objectives are, inter alia: national security requirements; the prevention of deceptive practices; protection of human health or safety, animal or plant life or health, or the environment. In assessing such risks, relevant elements of consideration are, inter alia: available scientific and technical information, related processing technology or intended end-uses of products.

435. It is likely that restrictions on GMOs will become a subject of contention under the disputes settlement mechanisms of the WTO and that the arrangements countries make will be subject to close examination there.

436. The use of trade measures to pursue environmental objectives has been part of the international landscape for nearly 100 years. For example in 1906 there was an international conference that adopted a treaty to stop the production and importation of matches made with white phosphorous. Environmental trade measures can be legally and effectively used to protect the environment. But the room within GATT for such devices remains unsettled and their use is likely to be controversial. As the *Report of the WTO Committee on Trade and the Environment* (November 8 1996) put it:

> … there is already scope under the WTO provisions to use trade measures for environmental purposes. These provisions aim to ensure that WTO members may adopt and enforce measures in pursuit of important public policy objectives for the protection of their environmental resources, while safeguarding members' WTO rights against arbitrary or unjustifiable discrimination and as far as restrictions on trade.

437. The locations of environmental harms are commonly separated into five categories:

- Domestic;
- Trans-boundary;
- Global;
- Foreign, resulting in loss of global positive externalities;
- Foreign.[196]

438. The prevailing opinion is that trade measures designed to remedy environmental harms that exist within a State's territory are usually considered legitimate. But the remaining four categories require some degree of external reach to remedy the environmental harm in question. Whether or not such an external reach is justified under the eyes of international law often turns on the jurisdiction of basis of the measure.

439. There is no doubt that considerable tension exists between the conflicting goals of environmental protection and trade liberalisation. These stem from three sources. The first is the different valuations of environmental priorities between

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[196] Daniel C Esty, *Green Gaps: Trade, Environment and the Future* (1994), pp. 121-26.

States. The second is the extra-territorial nature of global environmental problems and the extra-territorial nature of measures designed to remedy them. The third is the perceived incompatibility of free trade goals and trade measures directed at the environment.

440. There are a number of criteria that are used within the GATT/WTO framework to measure whether a national measure falls within the definition of "technical regulation" as that term is used in the Agreement on the Technical Barriers to Trade. These are:

- Whether the national measure is within the definition of "technical regulation";
- Whether, with respect to the terms of the measure, products imported from another member receive treatment no less favourable than the treatment received by similar domestic products, and by similar products imported from other countries;
- Whether the national measure has been prepared, adopted or applied to create unnecessary obstacles to international trade;
- Whether the circumstances that originally necessitated the national measure have changed so that the measure is no longer necessary;
- Whether the national measure is based on international standards unless special condition such as climatic or geographical factors require otherwise; and
- Whether the importing member considered whether a similar technical regulation of the exporting member could be accepted as equivalent.

441. It is not necessary to analyse for the purposes of this study, the obligations placed on New Zealand by international environmental law on the one hand, or World Trade law on the other. The issues exist; they are not resolved; and care needs to be taken to ensure that New Zealand does not get into difficulties by whatever regime it erects in relation to liability for GMOs. But it is not thought likely that what is recommended in this paper will cause international difficulties to arise.