

**PUBLIC DISCUSSION PAPER – IMPROVING THE OPERATION
OF THE HSNO ACT FOR NEW ORGANISMS
SEPTEMBER 2002**

**SUBMISSION BY RESEARCHED MEDICINES INDUSTRY
ASSOCIATION OF NEW ZEALAND INCORPORATED**

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PREAMBLE

The Researched Medicines Industry Association of New Zealand (RMI) is the professional and trade organisation of New Zealand's research-based pharmaceutical industry. Its 24 member companies are engaged in the research, development, manufacture and marketing of prescription medicines and the ongoing improvement of medical and scientific knowledge about their products.

New medicines developed by the pharmaceutical industry may contain active substances derived from conventional methodologies, or may be developed utilising genetic modification (GM) techniques. GM medicines can be sub-categorised as “GMO medicines” (contain a genetically modified organism in the finished dose form) or “GM-derived medicines” (manufactured utilising GM techniques, but do not contain a GMO in the finished dose form).

There are currently no GMO medicines available in New Zealand, though at least one such product is marketed overseas. However, with the advent of newer GM techniques, there is likely to be an increasing number of applications for new GMO medicines in New Zealand following discontinuation of the moratorium on GMOs in October 2003. Finished dose form medicines that do not contain a GMO are currently exempted from the provisions of the Hazardous Substances and New Organisms Act (HSNO).

Since RMI companies are principally involved in prescription medicines, the focus of this submission is the assessment of GMO medicines (Chapter 5 of the Discussion Paper) and liability issues relating to GMOs (Chapter 8). For reference, a copy of the RMI submission to the Royal Commission on Genetic Modification (October 2000) is enclosed with this submission.

EXECUTIVE SUMMARY

To date, GM medicines have not been shown to pose any greater risk than conventional medicines. Indeed, because of their often greater purity and specificity, GM medicines are likely to be safer and more effective than existing conventional medicines.

RMI supports the regulation of therapeutic products commensurate with the level of the assessed risk. For conventional medicines, this is achieved through a risk-assessment by Medsafe of the safety, quality and efficacy of products under the regulatory framework provided by the Medicines Act 1981 and Medicines Regulations 1984.

Looking to the future, New Zealand's utilisation of biotechnical developments must be flexible and grounded in a regulatory framework that enables appropriate, scientifically based, evaluation and control. RMI concurs with the strategy goal outlined in the Discussion Paper on the New Zealand Biotechnology Strategy¹, that the development and introduction of new biotechnologies should be managed "with a regulatory system that optimises opportunities and innovation while safeguarding health and the environment."

For these reasons, RMI concurs with the recommendation of the Royal Commission on Genetic Modification, and favours Option 2 under Chapter 5 of the Discussion Paper (i.e. approval of GMO medicines under the Medicines Act only). Multiple regulatory oversight by both Medsafe and ERMA would represent an unnecessary and costly duplication of effort.

Although the Discussion Paper proposes streamlining of the approval processes, it does not provide guidance on the likely extent of environmental impact data that would be required for any application for a new GMO medicine. This could have major cost implications for international pharmaceutical companies, which may choose not to conduct research activities to provide data solely for New Zealand purposes. The Discussion Paper rightly points out that the compliance costs of a [full] environmental assessment may result in these products not being available in New Zealand.

RMI concurs with the view of the Royal Commission on Genetic Modification that the current liability regime is adequate. The combined effect of current statutory regimes and civil/common law liability is sufficient to address potential harm from GMOs both in relation to personal and public risk. There has been insufficient investigation for the purposes of determining whether the

¹ New Zealand Biotechnology Strategy - Public Discussion Paper. Ministry of Research, Science and Technology; October 2002.

issues and risks associated with GMOs are so different from those associated with other activities or technologies that GMOs should be treated differently for liability purposes.

CHAPTER 5 ASSESSMENT OF GMO MEDICINES

5a Do you think that medicines that are or contain new organisms (including GMOs) should be subject to a streamlined approval process for release? Why?

RMI recommends that GMO medicines should be subject to a streamlined approval process for release.

To date, GM medicines have not been shown to pose any greater risk than conventional medicines. Indeed, because of their often greater purity and specificity, GM medicines are likely to be safer and more effective than existing conventional medicines.

Since Medsafe adequately manages the potential risks to humans of new medicines, there is a good argument for GMO medicines to be exempted from the provisions of the HSNO Act, in the same way that finished dose form medicines that do not contain a GMO are currently exempted from the Act. In any case, “*in vivo*” importation of GMO medicines would undoubtedly occur, because people entering the country may have been treated with the product whilst overseas.

Although the Discussion Paper proposes streamlining of the approval processes, it does not provide guidance on the likely extent of environmental impact data that would be required for any application for a new GMO medicine. However, it does state that “...it may result in medicines that are or contain new organisms undergoing a similarly rigorous risk assessment as currently provided for in the HSNO Act.” This could have major cost implications for international pharmaceutical companies, which may choose not to conduct research activities to provide data solely for New Zealand purposes. The Discussion Paper rightly points out that the compliance costs of a [full] environmental assessment may result in these products not being available in New Zealand.

5b If yes, which of the options described above do you prefer? Are there any alternatives that you can think of that reduce compliance costs but also adequately consider environmental issues and public consultation?

RMI concurs with the recommendation of the Royal Commission on Genetic Modification, and favours Option 2 (approval of GMO medicines under the Medicines Act only). This would provide the best outcome, for reasons of consistency, efficiency, cost-effectiveness and compliance.

Assessment by Medsafe of new medicines has been shown to provide adequate protection of the New Zealand public. Hence, the public can have confidence in the safety, quality and effectiveness of medicines that are marketed in this country.

Applications for new GMO medicines should be submitted to and approved by the Minister of Health, and should be subject only to the medicines legislation. Clearly, the medicines legislation would have to evolve in a timely manner to accommodate the emerging technologies. Since Medsafe does not have expertise to conduct streamlined environmental impact assessments, it may have to employ suitably experienced personnel or contract out this part of the evaluation. Its ambit might be restricted to a simple determination of whether a product crosses any specified threshold for environmental effects. If so, it could seek advice from ERMA or other (local or international) expert, as appropriate.

RMI notes that Medsafe and the Australian Therapeutic Goods Administration (TGA) have recently released a Discussion Paper on a proposal for a trans-Tasman agency to regulate therapeutic products². The joint agency would be established under a Treaty with Australia and would replace Medsafe and TGA. Any implementation of a regulatory regime for GMO medicines would have to take these proposals into consideration. It is worth noting that, in Australia, TGA is the principal agency regulating GMO medicines.

5c Do you think that conducting an environmental risk assessment that does not include some of the areas covered in the HSNO Act (e.g. economic or cultural considerations) would be an appropriate way of streamlining the approval process for these medicines? Why?

RMI favours a limited environmental risk assessment for new GMO medicines.

While RMI accepts that GMO medicines should have their environmental effects evaluated and any risks managed, the degree of regulation of such products should reflect their potential risks and benefits.

The potential risks of GMO medicines that should be taken into account in a regulatory framework would include personal risk to recipients, risk to the community and risk to the environment.

In the USA, where most biologics have been developed, GM medicines are manufactured in licensed facilities certified under Good Manufacturing Practice (GMP), with full oversight by the US Food & Drug Administration. Use of GMO medicines is most likely to be limited to individual patients under the

² A Proposal for a Trans-Tasman Agency to Regulate Therapeutic Products - Discussion Paper. Ministry of Health, June 2002.

guidance of a medical practitioner, with supply being controlled through their status as Prescription Only medicines. They are generally fragile compounds that require carefully controlled storage to maintain their efficacy, and generally biodegrade rapidly, which means that they pose no danger to the environment, even if released accidentally. Most biologic products are injectable, which are unlikely to be excreted into the environment.

5d Options 3 and 4 above propose to streamline the process by requiring only one formal application to the lead agency. Do you have a preference for which agency should lead the approval process: Medsafe or ERMA? Why?

Under 5b, RMI has recommended the implementation of Option 2 (approval under the Medicines Act only). However, if Option 2 were not chosen, RMI would strongly favour Medsafe being the lead agency in the evaluation of any application for a new GMO medicine (i.e. Option 3).

The evaluation of the safety, quality and efficacy of a new GMO medicine would form the majority of the overall evaluation, and evaluation by Medsafe would best ensure consistency with the evaluation of conventional medicines.

5e. What level of public participation and consultation should there be in the approval process for new organism medicines?

For the reasons stated under 5a-c above, RMI recommends that formal consultation should only be considered in the event that the approval of a new GMO medicine is expected to have a *significant* environmental impact. This could be highlighted during the evaluation by Medsafe, in consultation with ERMA.

5k Do you believe that human new organism medicines that have veterinary applications should be restricted to use in humans only?

RMI considers that a number of human GMO medicines may also have valuable veterinary applications and should not unnecessarily be constrained in their use. However, since GMO medicines used for veterinary applications would have a different risk:benefit profile to the same medicine used in humans, RMI recommends that animal remedies remain under the regulatory provisions of the ACVM and HSNO legislation.

CHAPTER 8 LIABILITY ISSUES

Statutory Liability

The use of genetic modification technology in New Zealand is controlled by HSNO and other statutes, such as:

- Resource Management Act 1991.
- Sale of Goods Act 1908.
- Fair Trading Act 1986.
- Consumer Guarantees Act 1993.

The HSNO Act provides for strict liability for certain offences and includes penalties and enforcement actions in the case of breaches of the legislation. This statute is dealing specifically with genetic modification technology. The strict liability offences in the HSNO Act are:

- Developing a GMO in contravention of the Act (e.g. failure to obtain ERMA approval to develop a GMO).
- Failing to comply with any conditions imposed by ERMA on an approval under the Act.
- Non-observance of a compliance order.

There are limited defences, such as reasonable actions to protect human life or health or to prevent serious damage to property or the environment. The various offences carry maximum penalties of three months imprisonment or a fine of \$500k, plus \$50k a day for continuing offences.

The HSNO Act confers wide-ranging inspection and enforcement powers upon authorised enforcement officers. It also provides for compliance orders requiring recipients to stop any dangerous conduct or actions contravening the Act, Regulations or controls under an approval.

The Resource Management Act has potential application to damage through genetic modification. Anyone can apply to the Environment Court for orders to prevent or stop any dangerous, offensive, objectionable or obnoxious activities that are or would be environmentally harmful. The Environment Court may also make parties responsible for any activities that are or would be

environmentally harmful, including any damage associated with such activities or remediation costs incurred in respect of such damage.

The Sale of Goods Act and the Consumer Guarantees Act require goods sold to consumers to be of merchantable and acceptable quality. There are statutorily implied undertakings to this effect in supply transactions. Moreover, a claim is possible for the negligent manufacture of a defective product.

Under the Fair Trading Act, there is liability for misleading and deceptive conduct where a product does not measure up to the claims that are made for it.

In relation to civil or common-law liability, there are three kinds of damage that may be caused by a GMO:

- Personal injury.
- Property damage.
- Financial economic loss.

In New Zealand, the possible application of the Accident Insurance Act 1998 needs to be considered at the outset, because all questions of liability for personal injury operate subject to the accident compensation regime that has been in force in New Zealand since 1974. Where the Act does not apply, the existing rules of liability for civil wrongs will determine whether and to what extent a defendant is subject to civil liability.

Where there is cover under the Accident Insurance Act, it is not possible to bring a claim for damages in respect of personal injuries or death caused by another. Conversely, where there is no cover under the Act, then an action for damages will lie.

For the purposes of the accident compensation scheme, it is likely that personal harm shown to have been caused by transgene technology, or some associated infection, would qualify as personal injury caused by an accident on a specific occasion. Damage caused by ingestion or exposure to GMOs over time would not be covered under the scheme, but a common law action would still be possible.

It is not intended in this submission to consider in depth the potential scope and application of the accident compensation regime. Suffice to note that there is also cover for personal injury caused by a medical misadventure and where a person suffers personal injury caused by a work-related gradual process, disease or infection.

Claims for Personal Injury Not Covered by the Accident Compensation Scheme

Where the accident compensation scheme does not apply, a claimant can bring a damages action based on:

- Negligence.
- Nuisance.
- The rule in *Rylands v Fletcher*.

Negligence

A negligence action can apply to property damage, or for economic loss caused by genetic modification techniques or products. In the absence of cover under the accident compensation scheme, the same principles apply to claims of personal injury. A claimant must show that there was a foreseeable risk of damage (in the sense of assumption of responsibility for that harm, or proximity in the relationship between the parties) that the defendant was negligent and that the negligence caused the harm. There must also be the absence of policy factors that may otherwise preclude recovery in negligence.

Any difficulties in this context will not necessarily be greater than those faced by claimants in negligence actions in other circumstances.

Where damage is done to land, this may give rise to liability in nuisance or under what is known as the rule in *Rylands v Fletcher*. These two doctrines tend to merge in modern times.

Nuisance

Where people use their land to carry out an activity that causes harm to the land of a neighbour, they commit nuisance. Liability depends on whether the interference is reasonable or unreasonable. An interference becomes unreasonable and actionable where it exceeds what an ordinary person could reasonably be expected to tolerate. Where damage is foreseeable, then liability is strict. Nuisance is a claim 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.

Rylands v Fletcher

This is an extension of the law of nuisance and applies to the "escape" from the defendant's land of something likely to cause damage. Liability is strict and

applies even if the defendant was not at fault or took all reasonable precautions to prevent the escape. 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. The possibility of escape and the consequent harm must have been foreseeable.

The courts have applied the principles of nuisance and *Rylands v Fletcher* to many different factual situations. Those that are analogous to the present circumstances include damage caused by weeds or sprays. It is likely that the courts will deal with new situations, such as a claim for damage to a crop caused by contamination from a neighbour’s genetically modified product by drawing on these well-established principles.

Existing liability rules are sufficient

The RMI acknowledges that there will be issues in terms of the existing liability rules in relation to GMOs, including:

- The potential for harm to a large number of people, or to the environment generally, rather than to a limited number of identifiable claimants.
- Identification of the person responsible for the harm.
- The need to show that harm to the claimant was reasonable foreseeable.
- The need to show that the relevant GMO caused the particular loss.
- Issues relating to quantification of losses.
- The cost and complexity associated with litigating GMO liability issues.

Notwithstanding these matters, the RMI believes that there is no compelling reason to change the status quo in relation to the statutory/common-law liability regimes. The reasons for this view are:

- The development of common law principles has shown an ability to keep pace with technological advancement.
- The courts have been well able to mould new remedies for novel situations and parliamentary intervention has rarely been needed in respect of the rapidly changing technology in the modern world.

- There is nothing so radically different in genetic modification from a legal liability perspective, as to require new or special rules or remedies.
- A specific, statutory regime that imposes strict liability can be an impediment to innovation and progress. The weight of international precedent is against establishing such a regime. The US, Canada, the UK and Japan do not impose strict liability and instead rely on the common law and general environment protection legislation for those seeking recourse. It is significant in this context that New Zealand's jurisprudence is similar to that applying in these first three countries.
- The existing liability rules are sufficient to encourage firms and individuals to take appropriate precautions to prevent or reduce harm from GMOs. This would include insurance and various mechanisms for encouraging appropriate precautionary steps in relation to GMOs. The HSNO Act already provides for a range of regulatory mechanisms in this context. The existing liability rules, coupled with the specific statutory/regulatory regimes are considered adequate to encourage appropriate precaution in relation to GMOs.
- With an appropriate emphasis on prevention, this should address sufficiently unforeseen or anticipated loss or damage through the use of GMOs.
- Liability issues are always difficult and there is a balancing exercise required between the competing interests of protection of the public and the environment on the one hand and on the other, the need, in the public interest, not to stifle innovation or discourage investors by imposing overly stringent conditions on research or economic activity.
- In the present circumstances, the appropriate balance can be struck by leaving the liability regime as it currently stands.

As already pointed out, the adjudication of claims arising from the use of GMOs calls for a constant adjustment of competing interests. Opposed to the claimant's demand for protection against harm is invariably the countervailing interest of the defendant not to be impeded in the pursuit of the defendant's own wants and activities. Hence, the administration of the law in this context involves a weighing of these conflicting interests in the scales of social value, with a view to promoting a balance that will minimise friction but be most conducive to the public good.

The type of damage or harm from the use of GMOs will often be different in each case. The types of cases in which the competing interests will clash will

also be variable and the social importance attached to the discrete requirements of the parties on any particular occasion will vary from one case to the next and in relation to each other. It therefore becomes obvious why a resolution of these conflicts in concrete situations cannot be achieved on the basis of any single formula, and currently there is no better substitute than the existing liability rules.