

**NEW ORGANISMS AND OTHER MATTERS  
(NOOM) BILL**

**SUBMISSION TO EDUCATION AND SCIENCE SELECT COMMITTEE  
BY THE RESEARCHED MEDICINES INDUSTRY  
ASSOCIATION OF NEW ZEALAND**

**13 June 2003**

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**1. INTRODUCTION**

- 1.1 The Researched Medicines Industry Association of New Zealand (RMI) is the professional and trade organisation of New Zealand's research-based pharmaceutical industry. Its 22 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.
- 1.2 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 either "GMO-medicines" (i.e. contain a genetically modified organism in the finished dose form), or "GM-derived medicines" (i.e. manufactured utilising GM techniques, but do not contain a GMO in the finished dose form).
- 1.3 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).
- 1.4 In November 2002, the RMI made a submission to the Ministry for the Environment on its Discussion Paper "*Improving the Operation of the HSNO Act for New Organisms*" (September 2002). A copy of the RMI submission and further information on the RMI can be accessed at: [www.rmianz.co.nz](http://www.rmianz.co.nz).
- 1.5 This submission focuses on the two main issues that impact on the medicines industry, namely:
  - Streamlining of the approval process for medicines that are or contain new organisms.
  - Liability issues for GMO-medicines once products are distributed in New Zealand.
- 1.6 In addition to this written submission, the RMI wishes to make an oral presentation to the Education and Science Committee.

**2. EXECUTIVE SUMMARY**

- 2.1 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 biotechnology techniques, there is likely to be an increasing number of applications for new GMO-medicines in coming years.

- 2.2 A 2002 survey<sup>1</sup> found that 371 biotechnology medicines were in development worldwide by 144 companies. These potential medicines were either in human clinical trials or under review by the US Food and Drug Administration. It is not clear how many of these medicines developed through biotechnology are GMO-medicines. The RMI is attempting to ascertain the number of GMO-medicines that are currently in development, for which applications for approval may in due course be submitted in New Zealand.
- 2.3 The 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.
- 2.4 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. The RMI concurs with the strategy goal outlined in the Discussion Paper on the New Zealand Biotechnology Strategy<sup>2</sup>, 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."
- 2.5 The Biotechnology Taskforce<sup>3</sup> has recommended that "Regulations must be efficient, cost effective and equal to international best practice and, where appropriate, must be acceptable to our major trading partners. Industry must have a regulatory environment that is transparent and predictable. New Zealand has one of the most comprehensive regulatory regimes in the world. However, compliance costs and delays related to public consultation are climbing. The public consultation process requires streamlining to improve cost and time overheads without compromising quality control."

### **Streamlining of the approval process for GMO-medicines**

- 2.6 The RMI fully supports the provision in the NOOM Bill for a separate fast-track system to deal with medicines required urgently to manage emergency situations (e.g. bio-terrorism).
- 2.7 The current requirement for dual evaluation of a new GMO-medicine by both Medsafe and ERMA imposes unacceptably high compliance costs on industry. The Royal Commission on Gene Technology noted that these costs may deter companies from marketing GMO-medicines in New Zealand, thus depriving New Zealanders of potential health and other benefits. The high compliance costs may also have adverse effects on a number of strategies designed to facilitate the growth of the knowledge economy and biotechnology sector in New Zealand.

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<sup>1</sup> New Medicines in Development - Biotechnology. Pharmaceutical Research and Manufacturers of America (www.phrma.org); October 2002.

<sup>2</sup> New Zealand Biotechnology Strategy - Public Discussion Paper. Ministry of Research, Science and Technology; October 2002.

<sup>3</sup> Growing the Biotechnology Sector in New Zealand – a Framework for Action. Report from the Biotechnology Taskforce; May 2003.

- 2.8 Although the Bill proposes streamlining of the approval processes for low risk GMO-medicines, the actual criteria for “low risk circumstances” have not yet been established and the medicines industry remains uncertain as to what level of regulatory control will be applied to GMO-medicines.
- 2.9 Because of the small size of the New Zealand medicines market, companies are unlikely to submit applications for new GMO-medicines if those applications may be subject to a full environmental assessment under the HSNO Act. The additional compliance costs associated with a full application to ERMA and public consultation procedures could well result in new innovative products not being available in New Zealand.
- 2.10 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 the use of GMO-medicines would probably be limited to individual patients on prescription by a medical practitioner, they would be unlikely to pose a danger to the environment.
- 2.11 The RMI recommends that applications for new GMO-medicines should be exempted from the provisions of the HSNO Act altogether. Instead, GMO-medicines should be reviewed and approved by the Minister of Health under the provisions of the Medicines Act. Applications should be subject to the usual assessment of safety, quality and efficacy, plus a limited assessment of environmental risk. The RMI believes this would provide the best outcome, for reasons of consistency, efficiency, cost-effectiveness and compliance. In any case, the degree of regulation of such products should reflect their potential risks and benefits.
- 2.12 The RMI has highlighted a number of flaws in the drafting of the amendments to the Medicines Act, consequential to the NOOM Bill. These flaws require attention to ensure a consistent approach to the regulation of GMO-medicines.
- 2.13 Possible additional controls on the supply of medicines with provisional consent to distribute and clinical trial supplies should not be so onerous that they restrict the availability of new medicines that may offer significant benefits for a limited number of patients, or stifle research investment by international companies in New Zealand.

### **Liability issues**

- 2.14 The RMI considers that there is no evidence that the 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.

2.15 The RMI concurs with the view of the Royal Commission on Genetic Modification that any potential adverse effects of GMO-medicines are adequately covered by the existing liability regime. 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.

### **3. STREAMLINING OF THE APPROVAL PROCESS FOR GMO-MEDICINES**

3.1 The NOOM Bill includes provision for a fast-track system to deal with medicines required urgently to manage emergency situations (e.g. bio-terrorism). The RMI fully supports this provision.

3.2 The NOOM Bill also includes provision for a streamlined approval process for new GMO-medicines.

3.3 Currently, a company wishing to market a new GMO-medicine would need to submit two applications: one to Medsafe (for evaluation of safety, quality & efficacy) and one to the Environmental Risk Management Authority (ERMA; for evaluation of public health and environmental effects). In its report the Royal Commission on Gene Technology noted that the high costs of this dual evaluation may deter companies from marketing GMO-medicines in New Zealand, thus depriving New Zealanders of potential health and other benefits. Officials have noted that the high compliance costs may also have adverse effects on a number of strategies designed to facilitate the growth of the knowledge economy and biotechnology sector in New Zealand.

3.4 The proposed legislation has three key elements:

- For GMO-medicines, criteria will be established to define “low risk circumstances”.
- For GMO-medicines that meet these criteria, ERMA will be given powers under the HSNO Act to delegate the consideration and approval of applications for GMO-medicines to another suitable lead agency (e.g. Medsafe).
- Approvals for GMO-medicines under the HSNO Act could be given by the lead agency with or without controls.

3.5 Although the Bill proposes streamlining of the approval processes, the actual criteria for “low risk circumstances” have not yet been established. The Bill provides little guidance on the likely extent of environmental impact data that would be required for an application for a low risk GMO-medicine. The minimum data set and standards requirements for a streamlined application are likely to be further developed in Regulations/guidelines but industry remains uncertain as to the actual level of regulatory control will be applied to GMO-medicines.

3.6 Where an application does not meet the low risk criteria (i.e. the medicine is assessed as posing a significant public health, environmental or cultural risk), a full application to ERMA, including public consultation, would be required. The Medsafe and ERMA evaluation processes could occur simultaneously, but the product could not be distributed until approvals under both the Medicines Act and HSNO Act had been given.

- 3.7 The current uncertainty is of major concern to the medicines industry. Until the level of regulatory control can be confirmed, it is unlikely that any company would choose to be the first to submit an application for a new GMO-medicine, particularly since the New Zealand market for medicines is very small by international standards. The potential requirement for a full environmental assessment and the associated compliance costs could well result in new innovative products not being available in New Zealand.
- 3.8 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.
- 3.9 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 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, and are unlikely to be excreted into the environment.
- 3.10 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 altogether, in the same way that finished dose form medicines that do not contain a GMO are currently exempted from the Act.
- 3.11 The RMI concurs with the recommendation of the Royal Commission, that GMO-medicines should be controlled only under the Medicines Act. The RMI believes this would provide the best outcome, for reasons of consistency, efficiency, cost-effectiveness and compliance. Assessment of new medicines by Medsafe 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.
- 3.12 The RMI recommends that applications for new GMO-medicines should be submitted to Medsafe and approved by the Minister of Health. Applications should be subject to the usual assessment of safety, quality and efficacy, plus a limited assessment of environmental risk. 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.

3.13 The Bill indicates that streamlined processes would be applied to applications for consent to distribute GMO-medicines under Section 20 of the Medicines Act. RMI notes, however, that there are a number of flaws in the drafting of the consequential amendments to the Medicines Act, in relation to supplies of GMO-medicines made under other sections of the Medicines Act:

- As drafted, the amendments do not indicate whether streamlined processes would be applied to applications for *provisional* consent to distribute GMO-medicines under section 23. Supplies of medicines under section 23 are already subject to regulatory oversight by Medsafe and distribution of these medicines cannot be made without the prior consent of the Minister of Health. Any additional controls on section 23 medicines would restrict the availability of new innovative medicines that may offer significant benefits for a limited number of patients.
- As drafted, the amendments do not indicate whether streamlined processes would be applied to applications for exemptions for clinical trial supplies under section 30. Supplies of medicines used in clinical trials are already subject to regulatory oversight by Medsafe and distribution of these medicines cannot be made without the prior consent of the Director-General of Health. Any additional controls on clinical trial medicines could stifle research investment by international companies in New Zealand.
- The wording of the amended exemptions in the Medicines Act for supply by practitioners (section 25), supply by pharmacists (section 26), herbal remedies (section 28), and supply by health practitioners (section 29) is incorrect and requires correction. As drafted, the amended exemptions would not allow supply of low-risk GMO-medicines under these exemptions, but *would* allow the supply of high-risk GMO-medicines, i.e. the *opposite* of what is probably intended by Government.

#### 4. LIABILITY ISSUES

- 4.1 The Bill proposes to impose both a *strict civil liability* rule for harm caused by non-complying activities and a *civil penalties regime* for certain breaches of the HSNO Act. This is intended to strengthen incentives to comply with the regulatory regime, without adding further industry compliance costs.
- 4.2 The strict civil liability rule would enable individuals to seek compensation for harm caused by GMO-medicines. It would cover cases where, for example, the necessary approvals under the HSNO Act had not been obtained or where conditions imposed by ERMA had deliberately not been complied with. In these cases, persons who have been harmed as a result of the breach would not have to prove negligence to be awarded compensation (i.e. civil liability regardless of fault).

- 4.3 The proposed liability regime is not in accord with the view of the Royal Commission, which recommended that there should be no change in the liability system in relation to GM products. The RMI concurs with the Royal Commission that any potential adverse effects of GMO-medicines are adequately covered by the existing liability regime.
- 4.4 In support of this view, the following text is reproduced from the RMI's submission to the Ministry for the Environment on its earlier Discussion Paper.

### **Statutory liability**

- 4.5 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.
- 4.6 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.
- 4.7 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.
- 4.8 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.
- 4.9 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.

- 4.10 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.
- 4.11 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.
- 4.12 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.
- 4.13 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.
- 4.14 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.
- 4.15 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.
- 4.16 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**

- 4.17 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**

- 4.18 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.
- 4.19 Any difficulties in this context will not necessarily be greater than those faced by claimants in negligence actions in other circumstances.
- 4.20 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**

- 4.21 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**

- 4.22 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.
- 4.23 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**

4.24 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.

4.25 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.

4.26 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.

4.27 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.