ERMA New Zealand
Evaluation and Review Report

To import, develop or field test in containment organisms with a range of genetic modifications and maintain these organisms in containment for research, breeding and for the production of products with potential commercial applications.

Applications: **GMC07012, GMD08012, GMD07074 and GMF07001**

Prepared for the Environmental Risk Management Authority

Executive Summary

AgResearch Limited submitted four applications to import, develop, and field test genetically modified (GM) organisms. The applicant requested that the approvals be granted for an unlimited duration and for use within indoor or outdoor containment facilities at unspecified locations.

The unlimited range of genetic modifications, techniques and traits proposed means that we cannot identify the range of GM organisms to be imported, developed or field tested.

Without being able to identify the range of GM organisms we are unable to undertake the assessment of effects as required by section 45 of the Hazardous Substances and New Organisms Act (the Act), including identifying the biological nature of the GM organism or the nature and degree or type of hazard intrinsic to those GM organisms. We also cannot properly assess the adequacy of the containment system proposed by the applicant as required by section 45 of the Act.

Therefore, we (the ERMA New Zealand staff) recommend that the Environmental Risk Management Authority decline the four applications.

Contents

1 The proposed activities

1.1 The applicant

1.1.1 AgResearch is the largest of the government-owned Crown Research Institutes (CRIs) with a history of agricultural research, having been formed from the Department of Scientific and Industrial Research (DSIR) and the technical wing of the Ministry of Agriculture (MAF Tech) in 1992.

1.1.2 Since 1998, AgResearch has received 16 genetically modified (GM) organism containment approvals, 133 GM organism development approvals and four GM organism outdoor containment approvals.

1.2 The applications

1.2.1 Applications GMC07012, GMD08012, GMD07074 and GMF07001 cover a range of activities indoors (eg, within indoor containment facilities such as laboratories) or outdoors (eg, within outdoor containment facilities such as secure outdoor enclosures) involving a range of GM organisms. Specifically:

- Application GMC07012 covers the importation of GM organisms into indoor or outdoor containment.
- Application GMD08012 covers the production of GM organisms within indoor containment. For the larger animals, this application is intended to cover the production of the GM embryos or GM sperm that would be transplanted or inseminated into surrogates and maintained in outdoor containment.
- Application GMD07074 covers GM organisms within outdoor containment.
- Application GMF07001 covers the field testing of GM organisms within outdoor containment.

1.2.2 The applicant stated that the purposes for which AgResearch would utilise these approvals *"will depend on the needs of the pastoral sector, commercial opportunities for transgenic livestock-derived products, the applications of transgenic technologies to those needs and consumer attitudes to particular uses of genetic modification."* (page 5 of application GMD08012). These purposes would include: to undertake research and production of therapeutic (eg, nutraceuticals and biopharmaceuticals), diagnostic or other commercially valuable products; to enhance livestock traits including productivity, welfare and sustainability; to develop animals as models for human gene function and physiology; and to research techniques to produce transgenic animals and investigate gene function.

1.2.3 The applicant requested that the approvals be granted for an unlimited duration and for use within indoor or outdoor containment facilities at unspecified locations.

2 Submissions

2.1.1 We received submissions from 1724 submitters. Of these, 1122 were based wholly or in part on submission templates (form submissions) provided by public interest

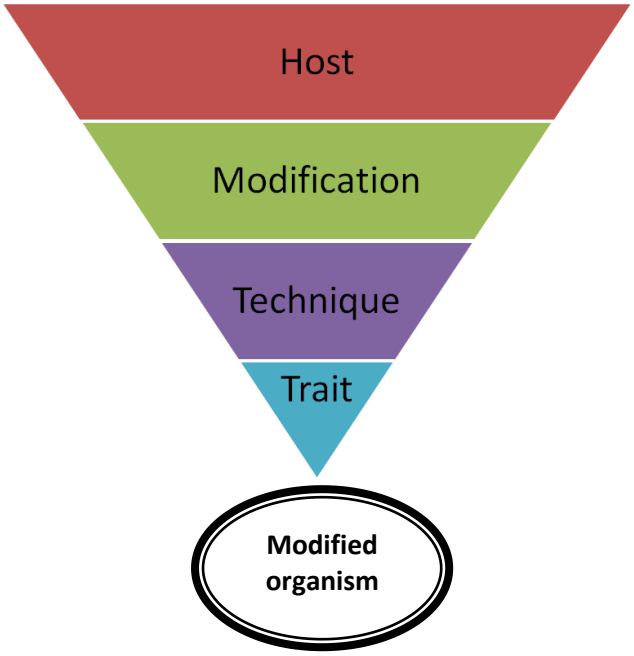
groups. We identified 45 substantive submissions. The major issues identified by submitters are summarised in the Appendix to this report.

3 GM organisms

3.1 Identification of the range of GM organisms

3.1.1 Before we can do a risk assessment, we need to identify the GM organisms. GM organisms are identified by describing the host organism, the genetic modifications made to the host, the techniques used to develop the GM organism and the traits exhibited by the GM organism. The figure below illustrates this pictorially.

Figure 1: The components of a GM organism



3.2 Host organisms

3.2.1 The host organisms proposed to be modified are:

- Indoor containment: non-pathogenic strains of *Escherichia coli* and yeast, a range of cell lines (including those sourced from African green monkeys and humans), and small and large animals from the following genera, excluding those listed by the Convention on International Trade in Endangered Species (CITES): *Bos*, *Bubalus*, *Ovis*, *Sus*, *Equus*, *Capra*, *Lama*, *Cervus*, *Rattus* (excluding kiore), *Mus*, *Cricetulus*, *Cricetus*, *Mesocricetus*, *Cavia*, *Oryctolagus*, *Trichosurus* and *Gallus*.
- Outdoor containment: large animas from the following genera: *Bos*, *Bubalus*, *Ovis*, *Sus*, *Equus*, *Capra*, *Lama* and *Cervus* (excluding those listed by CITES).

3.3 Modifications, techniques and traits

3.3.1 The applications contain examples which illustrate the range of genetic modifications, techniques and traits to be used. However, as these examples are not exhaustive, the possibilities are unlimited.

3.4 Assessment of the GM organisms

3.4.1 A number of submitters considered that the applications did not contain sufficient information to clearly describe the GM organisms. For example:

"*There is insufficient information with the application to assess the hazard that such imported specie* [sic] *will present to other species currently in New Zealand (for example, there is no information about the precise nature of the genetic modifications that are intended nor about safety measures to ensure their containment.)*" [11249, Dr Mairi Jay]

3.4.2 Section 45 of the Act requires an assessment of whether the beneficial effects of having the organism in containment outweigh the adverse effects of the organism.

3.4.3 We made a number of attempts to define the range of GM organisms in order to allow an assessment of the effects of the organism to be undertaken. This included on 21 July 2008 requesting that the applicant list the organisms and describe the type of genetic modification, trait, product, or activity, and what the direct benefits of each of these GM organisms would be. The applicant replied that:

"….. at this time, AgResearch cannot provide an exhaustive list of GMOs that will be produced or the benefits thereof."

3.4.4 We then considered ways of altering the applications to enable an assessment of the effects of the organism to be undertaken. However, we considered that the level of alteration necessary to enable an assessment of effects to be undertaken would significantly change the nature of the applications. Therefore, we consider it is inappropriate for us to propose such limitations.

3.4.5 The unlimited range of genetic modifications, techniques and traits proposed means that we cannot identify the range of GM organisms to be imported, developed or field tested.

3.4.6 Without being able to identify the range of GM organisms we are unable to undertake the assessment of effects as required by section 45 of the Act, including identifying the biological nature of the GM organisms or the nature and degree or type of hazard intrinsic to those GM organisms.

4 Containment

4.1 Containment Standards

4.1.1 In all four applications, containment has been described based on the following standards for containment of the GM organisms (the Containment Standards):

- MAF/ERMA New Zealand Standard *Facilities for Microorganisms and Cell Culture: 2007a* (the Microorganism Standard);
- MAF/ERMA New Zealand Standard *Containment Facilities for Vertebrate Laboratory Animals* (the Vertebrate Standard); and
- MAF/ERMA New Zealand Standard *Containment Standard for Field Testing of Farm Animals* (the Field Testing Standard).

4.1.2 The applicant has also proposed containment controls in addition to the requirements of the Containment Standards (eg, the handling of milk obtained from GM organisms) and has supplied information on standard operating procedures, such as the training manual for the specialised PC2 containment facility where viral vectors are produced and handled.

4.1.3 The Containment Standards cover both physical and operational procedures necessary to contain GM organisms or viable material, to exclude unauthorised persons and other organisms from the facility, and contingency measures in an event of breach of containment. The Microorganism and Vertebrate Standards refer to various aspects of the Australian/New Zealand Standard 2243.3:2002 *Safety in laboratories Part 3: Microbiological aspects and containment facilities* (AS/NZ 2243.3:2002). The objective of this Standard is to promote safety in laboratories.

4.1.4 Some of the proposed GM organisms are not covered by existing Containment Standards. For example, the Field Testing Standard specifies the fencing requirements for the outdoor containment of sheep, goats, cattle, alpaca, llama and deer. However, the fencing requirements for pigs, water buffalo and equines are not specifically addressed.

4.1.5 The Field Testing Standard covers some of the GM organisms that the applicant has sought approval for but it does not cover all of them. On 21 July 2008, we requested information from the applicant on how these gaps in the containment system would be addressed. The applicant's response was that any gaps would be identified and appropriate containment measures would be agreed with MAF on a case-by-case basis. We consider that this proposal is inappropriate as it would involve the delegation of decision-making to an entity other than the Environment Risk Management Authority.

4.1.6 We therefore consider that we cannot properly assess the adequacy of the containment system proposed by the applicant as required by section 45 of the Act.

4.2 Location

4.2.1 The approval is sought for multiple unspecified locations for the indoor and outdoor containment components.

4.2.2 On 21 July 2008, we requested the applicant to specify the location of the potential outdoor containment sites and the outcome of any consultation regarding those sites. The applicant replied that some work would be undertaken at Ruakura but that other locations would be looked at in future and therefore the applicant could not exhaustively describe the sites that would be used for the importation, development and field testing.

4.2.3 The lack of specified locations was one of the biggest concerns of submitters. For example:

- Federated Farmers of New Zealand stated that "*Federated Farmers is concerned that the exact locations of the proposed facilities have not been identified, and the affected landowners/communities have not been consulted. We understand that this is a generic application and that AgResearch does not think that it is necessary for it to identify the locations as the risks have been identified, but we disagree. Each region in NZ is unique and has different challenges. Placing all the regions in one generic basket is irresponsible and could lead to distinctive risks being missed and not rectified. This situation would place the region/s and research at risk.*" [#11254]

4.2.4 Many of the iwi/Māori consultees and submitters were opposed to the application and quoted the lack of specified locations as a key concern inhibiting their ability to undertake cultural impact assessments which may be considered to be highly site specific. The National Māori Reference Group established by AgResearch during its Māori consultation resolved that AgResearch needs to *"acknowledge the uniqueness of each iwi, hapū and whānau and the need for AgResearch to work directly with tangata whenua of any proposed containment site"*. This was further reinforced by submitters including:

- Te Rūnanga o Ngāi Tahu who noted concern with "*The lack of specificity of future research locations and manawhenua consultation for these specific sites. This is an example of open-endedness that is unacceptable and potentially undermines the kaitiaki role of whānau, hapū and/or iwi to exercise their judgement in regard to the impacts on cultural values associated with their takiwā*[1]*. In the case of Ngāi Tahu, there is a requirement to be specific in regard to location of where the research will be conducted and consultation with the relevant manawhenua is a necessity.*" [#11508].

4.2.5 Ngā Kaihautū Tikanga Taiao commissioned a report[2] reviewing the pre-application consultation process undertaken by AgResearch in relation to these applications. The report outlined similar concerns to those raised by submitters and noted that

[1] Area.
[2] Dyana Jolly Consulting 2008. *Review of the pre-application consultative effort undertaken by AgResearch to engage with Māori for the purpose of ERMA applications GMC07012, GMC07074, GMC08012 and GMC07001.*

"the generic nature of the application proved a significant barrier to the ability of Māori to respond".

4.2.6 We agree that the unspecified locations in these applications provided a substantial challenge for submitters and iwi/Māori consultees to fully understand and evaluate the risks and benefits of these applications.

5 Conclusion

5.1.1 For the reasons outlined in sections 3.4.6 and 4.1.6, we (the ERMA New Zealand staff) recommend that the Environmental Risk Management Authority decline the four applications.

Appendix - Summary of the main themes raised in submissions and the comments from the Department of Conservation and the Ministry of Agriculture and Forestry

Summary of the main themes raised in submissions

A. Environment

Potential effects, concerns or issues	Illustrative quotes
Concern that GM animals may have adverse effects on the environment, ecosystems, native or other valued species	*"... AgResearch will be adding new species to a system that has co-evolved over billions of years. How can they be sure that adverse reactions and multiplication between bacteria won't occur over time? .... Scientists, even now, are only familiar with a small fraction of existing soil organisms, so how can AgRes predict that accidental release wont affect a native organism that hasn't even been identified or studied yet?*" [10428, Dr Susanna Lyle] "*Why should we risk so many other important characteristics of what makes us Kiwi by allowing something so fundamentally uncontrollable into our ecosystem? The native flora and fauna that we currently have is still declining, but the remainder are so delicately balanced in our climate that to upset that balance would be a death sentence for many.*" [11029, Erin Crowley] "*Genetic modification in any form is very dangerous, as it would result ultimately in a decline in genetic biodiversity.*" [11210, Jane Simmons] "*The genetic modification of rats, mice, hamsters, guineas pigs, rabbits, and possums as research models involve risk of escape and breeding. Without extreme care, we could end up with new animals that pose as much risk to the environment as stoats, weasels etc did when they were introduced.*" [11249, Dr Mairi Jay] "*The escape is also a real risk, particularly in the case of rabbits or possums……. New Zealand's experience in the difficulty of controlling possums and rabbits speaks for itself. The Applicant now wishes to add the risk of genetically modified possums to the risk to our native flora and fauna*." [11360, Greenpeace New Zealand Inc]
Concern that GM may have adverse effects on animal health	"*There is a risk of creating new diseases by experimenting on New Zealand animals which are currently free of BSE (Mad Cow Disease) and Scrapie.*" [10260, Leo Adler] "*As there is consideration of experimenting in field tests with rabbits, possums, rats and mice, there is also a risk of disease into wild populations, as well as into farm animals of other species listed*." [10433, Barbara Little]
Concern that GM animal waste disposal may have adverse environmental effects	"[*The applicant] openly claims there is no need to treat transgenic waste-materials (like milk) prior to final disposal.*" "*With complete disregard for common environmental responsibilities, AgResearch brazenly proposes, resting on its claimed experience over eight years, that the disposal of GE-animals and wastes from a field containment facility (e.g. Ruakura site) does not now need to be restricted to the field containment site and proposes that disposals be made at off-site (no controls) locations.*" [10392, Physicians and Scientists for Global Responsibility] "*The Applicant does not even want to be constrained in its disposal of matter which may contain genetic material...That this is reckless and dangerous is patently obvious.*" [11360, Greenpeace New Zealand Inc] "*It is wrong to allow GE animal waste for compost or to be sprayed onto fields.*" [11554, Avril Warren]

Potential effects, concerns or issues	Illustrative quotes
Concern that the escape of GM material from containment by HGT may have adverse effects on valued species	"*To my knowledge, there is no investigation of HGT into animals or no evidence of this in their monitoring reports. Until AgResearch addresses this issue, and corrects the inadequacies, then this, and any other, applications should be denied outright…. Other sites will probably be in more rural settings and animal populations greater outside with increased risk of HGT to those animals. Therefore applications must be on a case-by-case basis.*" [10375, Frank Rowson] "*AgResearch has a statutory obligation to provide full details of the genetic constructs of all genetically modified organisms to be used, whether new or imported, as an integral feature of each application to ERMA. This way ERMA may reasonably expect AgResearch to be diligent and come forward with details of the monitoring methodologies to be involved that use reporter-gene systems that are realistically capable of in situ detection and quantification of HGT in GE-hotspots such as soil at GE disposal sites*." [10392, Physicians and Scientists for Global Responsibility] "*One of the main environmental risks is the possibility of horizontal gene transfer (HGT) of GM DNA into soil biota and other micro-organisms.*" [11289, Philippa Jamieson]

B. Human health and safety

Potential effects, concerns or issues	Illustrative quotes
Concern that there may be adverse effects on human health from spread of new or more virulent diseases	"*Animals, especially pigs being bred as spare parts for humans creates danger for both animals and humans of new disease crossing the species barrier or 'xenotropic' organisms creating new diseases*". [10319, Kellie McGhie] "*NEW AND POTENTIALLY DANGEROUS VIRUSES MAY EMERGE.*" [10391, Julia Struyck]
Concern that the products of GM organisms may have adverse effects on human health and safety	"*New allergic reactions may also be caused."* [11360, Greenpeace New Zealand Inc] "*…. how can we justify the risk of unknown problems arising especially based on the established health concerns of current GE foodstuffs.*" [10870, Dr Mark Edmond] "*Drug development and manufacture is normally a very tightly controlled process, with strict safeguards in a specialised environment. This project suggests a casual, sloppy way of manufacturing pharmaceuticals, in that animals could be expected to be excreting active drugs into the environment during the research phase – and beyond if they make it to commercial production. This has very significant implications for contamination of ground water and risk of transfer to the food chain....*" [11498, Dr Anne MacLennan]
Belief that transgenic technologies may lead to human health benefits	"*[Transgenic] technologies also provide the opportunity to develop new animal models for studying human diseases, provide new systems for the production of therapeutics for ameliorating or controlling human illnesses and disease (e.g. insulin, factor XIII, growth hormone and other critical hormone based therapeutics). Finally, at a more fundamental level, transgenic organisms provide an important tool for studying gene regulation and function.*" [10426, Professor Neil Gemmell] "*...the transgenic programme represents a key part of the broader suite of technologies necessary to deliver products to achieve solutions to the major human health concerns identified above*" [10423, Dr Steve Hodgkinson]

C. Relationship of Māori to the Environment and the Treaty of Waitangi

Potential effects, concerns or issues	Illustrative quotes
Concern that there may be adverse effects on Māori cultural practices and values (eg kaitiakitanga, rangatiratanga, whakapapa, mauri, whanāungatanga etc)	"*The applications will diminish the rangatiratanga[3] of the Ngati Wairere hapu[4] due to the generic nature of the applications and the unlimited timeframes sought. In addition it severs the whakapapa[5] links of the people of Ngati Wairere as well as diminishes the kaitiakitanga[6] practices of the hapu.*" [10441, Te Kotuku Whenua Consultants] "*The genetic modification of animal species and in particular the transfer of genetic material from human cells is repugnant to tikanga maori[7] as it does not give due respect to the Mauri[8] of the species and the hau[9] inherent in the material. Furthermore the active breeding of genetically modified species means unacceptable interference with the natural progression of whakapapa.*" [10460, Pura Currin] "*Genetic engineering threatens Te Ira Hinengaro (the continuity of consciousness) by introducing un-natural phenomena thus breaking the chain of events stretching across time and space.*" [10912, Te Waka Kia Ora] "*From our perspective as a Maori organisation, it is within the main principles of mauri (life essence), whanaungatanga (family connectedness) and whakapapa (ancient lineage) that we raise our absolute disagreement regarding genetic engineering and GMO's. If these principles are damaged or tampered with in any way upsetting the holistic world balance, so too will be the mauri, whanaungatanga and whakapapa of Maori and following generations.*" [11348, Percy Tipene] "*Genetic engineering is a form of human colonisation that has the immediate effect of corrupting the Whakapapa (Genealogy) and Mauri (life force) of the targetted flora and fauna, .*" [11363, Te Runanga o Te Rarawa]
The applications/GM organisms are a breach of Te Tiriti o Waitangi (the Treaty of Waitangi)	"*Genetic engineering threatens to exploit Matauranga Maori (Maori knowledge) and flora and fauna resources for the benefit of others who have no interests in protecting the Treaty rights of Maori.*" [11363, Te Runanga o Te Rarawa] "*The Treaty of Waitangi Article 2 guarantees me '…undisturbed possession…' I regard genetic disturbance as the most fundamental kind of disturbance affecting the whole of the country, not just the area around Ruakura,…It would be a breach of my Treaty rights under Article 2 of the Treaty of Waitangi to grant the application.*" [11494, Jan Anaru]
Concern that there may be GM contamination of Māori-based organic products	"*GMO pollution threatens Te Hua Maori (natural produce) and indigenous organic farming production of food, clothing and housing.*" [10912, Te Waka Kia Ora] "*TWKO strongly oppose the applications that have the potential to undermine or ensure that growers can continue to grow and market non-GM products without any fear of contamination.*" [10912, Te Waka Kia Ora]
Impacts of inadequate consultation with Māori and provision of sufficient information	"*The time frames set to undertake consultation to maori was completely unreasonable along with the minimalistic amount of information.*" [10441, Te Kotuku Whenua Consultants] "*we do have some particular concerns….The lack of specificity of future research locations and manawhenua consultation for these specific sites. This is an example of open-endedness that is unacceptable and potentially undermines the kaitiaki role of whānau, hapū and/or iwi to exercise their judgement in regard to the impacts on cultural values associated with their takiwā[10]. In the case of Ngāi Tahu, there is a requirement to be specific in regard to location of where the research will be conducted and consultation*

[3] Absolute authority.
[4] Sub-tribe.
[5] Cultural identity or genealogy or ancient lineage.
[6] The abilityof Māori to act as stewards or caretakers.
[7] Māori protocols.
[8] Spiritual integrity or life force or life essence.
[9] Soul.
[10] Area.

Potential effects, concerns or issues	Illustrative quotes
	with the relevant manawhenua is a necessity." [11508, Te Rūnanga o Ngāi Tahu] "*Consultation to maori was meaningless. AgResearch failed to advertise the hui appropriately along with badly chosen venues. The hui were not held in regions that gave maori the opportunity to participate and has not given confidence to maori; particularly and firstly, that upholding the Tiriti o Waitangi relationship between the Crown entities and the Maori Tiriti partners are to be paid much heed.*" [10912, Te Waka Kia Ora] *"….I believe there needs to be an open iwi by iwi consultation process, with adequate advertising and publicity within the Marae systems and amongst Iwi leaders so that every Maori member of society feels that they have been consulted and had the chance to understand the application and how that relates to their cultural belief systems, and that subsequently their voice has been heard.*" [11237, Michelle McGregor] "*Applicant has failed to provide specific information on organism and gene descriptions for informed submissions by the general public…. Lack of specific information does not allow submitters to adequately identify the risks.*" [10441, Te Kotuku Whenua Consultants] "*we do have some particular concerns….The lack of specificity linking specific health, environmental or economic benefits of the proposed research to the necessity to incorporate a broad range of particular transgenic animals in these applications. The case for this expansion is unclear and once again reflects the open-ended style that is of concern to* Te Rūnanga o Ngāi Tahu*.*" [11508, Te Rūnanga o Ngāi Tahu] "*We do not believe as a whanau that we have enough information to make informed decisions about the proposed trials given that the risks; ehtical, moral, physical, spiritual have not been fully explored nor the sustainability or impact over time of such experimentation on the whanau/ families or communities of the people proposed to be involved in these trials.*" [10962, Te Whanau Philip-Barbara]
Concern that there may be adverse impacts of having applications with unlimited time duration on kaitiakitanga	"*The open-ended timescale of the current applications seeking indefinite approval is inappropriate. This mitigates against the capacity of Ngai Tahu and/or whānau, hapū and iwi to review the benefits and downsides of the proposed research and fails to recognise the function of the kaitiaki role of manawhenua*." [11508, Te Rūnanga o Ngāi Tahu]

D. Society and community

Potential effects, concerns or issues	Illustrative quotes
Belief that there will be adverse effects on personal or community values from the GM animals	"*New Zealanders have not had the opportunity to debate and decide whether GE products and organisms are wanted...Therefore, no level of risk should be accepted in the name of GE research*" [10784, Thomas Nixon] "*The public have a right to be concerned about the ethics of using animals*". [10295, Denyse Cambie] "*Testing animals is cruel and unnecessary*." [10926, Sarah Sutherland] "*The traditional use of domestic animals was for meat, fibre and milk and companionship. The relationship between humans and domestic animals should be one of respect and gratitude. The manipulation of animals by gene transfer and cloning reduces that relationship to one of exploitation and they become units of production.*" [10848, Patricia Scott] "*….the risk that individual animals will suffer unnecessarily for dubious commercial gain.*

Potential effects, concerns or issues	Illustrative quotes
	Some of the wide range of species listed are clearly capable of both physical and emotional distress." [10498, William Moore] "*I have concerns about animal welfare: transgenic trials often result in high mortality rate and unnecessary suffering to animals.*" [10428, Dr Susanna Lyle] "[*The application]....offends me on religious and ethical grounds.*" [11119, Jane Schaverien] "*I think it is an abomination that scientists are allowed to meddle with nature i.e. transferring genetic material from one species to another and the like*." [10761, Mischele Rhodes] "*The insertion of human DNA into other species is ethically repugnant to me*". [11289, Philippa Jamieson]
Concern that there may be adverse effect on New Zealand's image and reputation (in a non-economic sense) from the GM animals	"*The mere presence in this country of GM stock would be an insult to our "clean, green" image.*" [10764, Jacqui Tyrell] "*Obviously GM Undermines the New Zealand Brand.*" [11238, Jarad Bryant] "*New Zealand's image will be damaged. There is a risk of stigma, impacting our reputation.*" [11745, Wayne McKay]

E. Market Economy

Potential effects, concerns or issues	Illustrative quotes
Concern that the existence of GM animals may have adverse effects on the markey economy due to damage to New Zealand's brand image and reputation	"*As someone who is very involved in our important tourism industry I feel we should be doing everything within our power to promote New Zealand's 100% Pure image.... many clients I speak to ....are impressed with the natural goodness and perceived lack of GM foods over here*." [10272, Lesley Fallon] "*Many of our target markets for tourism are genetic engineering free nations themselves, and they travel great distances to see a country which is unique, and in many ways untarnished, like no place on earth. Introducing GE threatens that image and threatens the unique nature which tourists come to see. The tourism industry is worth too much to New Zealand to risk*." [10480, McManus Tourism Communications] "*Overseas markets overwhelmingly show that they are not interested in GM products and allowing them into our food chain will ultimately denigrate our image of producing clean, green products.*" [10445, Jules Clark] "*New Zealand's future economic and environmental future depend on this country remaining GE free. GE testing, research and commercial use will have a negative financial impact on our agriculture and tourism industry. New Zealand's status a a clean green place to visit and import and purchase agriculture and food products will be irreversibly harmed, damaging our economy and reputation*." [11050, Fiona Heares] "*introducing a GMO into the New Zealand dairy sector has the potential to cause a minimum of NZ$539.6 million in losses to the dairy and tourism industries. Thus, such a biopharming endeavour would need to offset those losses before it could be viewed as a net positive for the New Zealand economy*." (Kaye-Blake et al., Lincoln University AERU. 2007); quoted in [11358, Sustainability Council of New Zealand] "*Most New Zealand exporters stand to be negatively affected if New Zealand becomes known as a GM-using country, and this includes many of New Zealand's fastest growing 'glamour' brands such as Orca, Icebreaker, and Karen Walker, as well as established*

Potential effects, concerns or issues	Illustrative quotes
	stalwarts such as Canterbury, MacPac, Air NZ and the All Blacks. If New Zealand becomes a recognised user of GM technology, then the brand equity of 'New Zealand' will be degraded, creating problems of varying degrees for a wide variety of local brands and exporters". Jonathon Dodd, National Business Review, October 2003, quoted in [11358, Sustainability Council of New Zealand]
Concern that the existence of GM animals may have adverse effects on organic farmers and GE free producers	"*This is a small country, with an increasing amount of organic agriculture and permaculture being used by Transition towns, farmers and individuals that could be adversely affected by the use of GM*." [10280, Sara Dickon] "*I challange you to find an example of GE technology that has been implemented in a comercial environment that has not adversely affected Organic growers*." [10470, Dan Salter] "*The future of farming lies in high-value premium productions – including verified or certified Hua Parakore, hua Maori ara organics products – rather than 'lowest common denominator' genetically modified products which are expensive, risky and controversial to both develop and bring to market. By turning down genetic modification field trials, New Zealand stands to gain a competitive advantage over other countries which have already forfeited their food chain to GM contamination.*" [11348, Percy Tipene] "*[The applications] destroy the obvious potential for significant growth of organic farming in a world hungry for pristine primary produce."* [11984, Campbell MacDuff]
Concern that there may be economic losses from clean-up costs if anything goes wrong	"*the risk to the economy from any contamination arising from the genetically modified animals or their waste and resultant costs of clean-up should not be one that New Zealand public should have to bear*." [10460, Pura Currin] "*It is not OK for overseas biotech investors to exploit New Zealand as an experimental playground when the public is liable for clean-up costs when things go wrong.*" [10866, Hilary Campbell] "*It is simply not right for these investors to use NZ as an experimental testing ground for Genetic experiments when the public is liable for any costs of clean-up if things go wrong.*" [11238, Jarad Bryant]
Belief that there may be potential economic benefits from the GM animals	"*The use of animals to produce high value therapeutic solutions is both economically sensible for NZ but also a very realistic model to lower the production cost and availability of these therapeutics to members of the world population that can not currently afford traditionally manufactured solutions.*" [10821, Derek Fairweather, Innovation Waikato] "*Biotechnology is a crucial fledgling industry which New Zealand should be wise to take an active role in. Genetic engineering has unlimited potential and as long as contained adequately we should encourage this research.*" [10935, Robert Moore]
Belief that the research will not impact on image or trade	"*The LSN notes that these applications all involve work in containment. Therefore the impact to trade is likely to be negligible. There have been no negative trade effects from the current work*". [11211, Life Sciences Network] "*Development of GM technology in New Zealand seems most unlikely in itself to harm perceptions of the country image of New Zealand in regard to international markets for food products (or indeed non-food products) sourced from New Zealand*." [11942, Associate Professor John Knight]

F. Other matters

Issues and concerns	Illustrative quotes
Concern that the applications are very general, broad in scope, vague, lack specific information or detail	"*I am concerned at the broad ranging nature of this application....the application lacks sufficent boundaries on experiments, length of trials, specific information on which species involved and geographic sitings of the proposed modified species....I would certainly hope that such a vague submission that has potentially wide ranging ramifications is denied*." [10994, Katie McCutcheon] "*There is insufficient information with the application to assess the hazard that such imported specie will present to other species currently in New Zealand (for example, there is no information about the precise nature of the genetic modifications that are intended nor about safety measures to ensure their containment.)*" [11249, Dr Mairi Jay] *"...exclusion of information [on specifics of genetic modifications] precludes the ERMA Authority from foundation material that could enable it to determine and evaluate risks to public health from transgenic livestock...Realistic assessment of transgenic constructs in terms of risk probability is impossible.*" [10392, Physicians and Scientists for Global Responsibility] "*I believe [the application] to be far too broad in scope, duration, is poorly prepared, and suspect in its inculsion of humans as a host for genetic modification. The proposal put forward is sufficiently broad that is passing would be almost without limitations. That they have not provided even rudimentary details of when/where/how long suggests they either do not know this information or are better off hiding such details. Either way, this doesn't instill trust in their ability or desire to protect the country from the potential harm resultant from such study*." [11002, Sara McInally] "*The applications are generic in nature and do not provide sufficient information for submitters or the Authority to properly assess the intent, risks, or benefits.*" [11336, Jon Carapiet] "*The main reason for my submission is that is insufficient information in the AgResearch application for ERMA to undertake an adequate risk assessment, and the application should be declined on these grounds. Essentially, because submitters have no access to full and clear information on genetic constructs, location and disposal (and nor, it seems, does ERMA), this application should not have been notified until these matters were clearly dealt with.*" [11349, Scott Willis] "*This is an amazingly broad and loose application, seeking approval for multiple recipient animals, multiple donor sources, and unlimited gene transfers over unlimited time. The potential for unexpected events is enormous. ....There is far too much flexibility and vagueness. If approved, this would give AgResearch almost unlimited scope to pursue different directions in research without further consultation. It gives the impression of casting a net as widely as possible, hoping to catch that commercial gold*." [11498, Dr Anne MacLennan] "*Overall, the research finds that risks and benefits cannot be adequately assessed independently of the specifics of the activity and of the context in which the activity will occur. The findings contest the applicant's assertion that risks can be assessed on a generic basis, without specification of the organism, the site or the ownership and management structure of the operation.... because the application is so open-ended and under-specified, the benefits are purely speculative and the likelihood that they will be attempted, let alone achieved, cannot be adequately evaluated..... In summary, our research indicates that the application cannot be adequately assessed in its current form.*" [11521, Dr Joanna Govern] "*It is impossible for ERMA or submitters to consider the details because there are none. This is a 'generic' application. It should not have been accepted, and cannot be approved.*" [11974, Peter Born] "*There is not enough risk information to allow this to be approved*." [11976, Debbie Verdonk]

Issues and concerns	Illustrative quotes
	"*There is inadequate information on genetic constructs, location and disposal for ERMA to make a good decision, or for submitters to make an informed submission, and ERMA should not have notified this application until these matters were adequately specified.*" [11993, Jennifer Mulcock] "[*The applications] are so broad in scope and lacking in specific details, that no realistic or adequate risk assessment can be derived for them.*" [11994, Friends of the Earth (NZ)] "*This list of animals and microbes is too large. If AgResearch does need to use all these animals, more specific and rigorously worded submissions need to be made for each animal/microbe separately to justify their usage. This list reads like AgResearch have simply jotted down a long list of possibles to provide future opportunities to decide which directions to go in. Surely a much more detailed and accurately presented case needs to be made to justify so many organisms being listed? Surely they have their future research plans detailed?*" [10428, Dr Susanna Lyle] "*The purpose of the application was so broad we were challenged to find what could be excluded from this group of applications.*" [11280, Sustainable Future] "*This application is wide ranging and indefinite in its desire to experiment genetically with such a variety of animals and experiments. Cited aims are vague.*" [10747, Royal Forest and Bird Protection Society]
Concern that the applications do not meet the requirements of the HSNO Act	"*This application does not fulfill the requirements of the HSNO Act.*" [10600, Marie Hellyer] "*The failure to identify each GMO is a barrier to assessing risks and was not within the spirit of the HSNO legislation.*" [11280, Sustainable Future] "*AgResearch has not presented valid applications with respect to HSNO s40(2) or the requirements of the Methodology.*" [11358, Sustainability Council of New Zealand Inc]
Concern about the unlimited duration of approvals sought by the applicant	"*There is a new scale of risk in the range of animals, locations, and unlimited timeframe being proposed.*" [11795, Lars Weckbecker] "*Unlimited time duration is a breach of natural justice and the intent of the purpose of the Act.*" [10441, Te Kotuku Whenua Consultants] "*No approval should be of unlimited duration. That leaves no opportunity to call a halt to the research should it transpire that it is harmful*." [11494, Jan Anaru]
Belief that the unlimited duration of approvals sought are reasonable	"*...an unlimited approval seems reasonable given the cost, uncertainty and diversion of effort a notified application process involves*." [10798, Professor Paul Atkinson] "*The LSN does not consider that approving this application for an unlimited time period will significantly increase the relative risks. It is noted that ERMA has the ability to change the conditions of the approval if new information comes to light. ERMA could also impose time controls or reporting requirements to certain aspects of the application which it considers has less certainty.*" [11211, Life Sciences Network]
Concern about applications seeking approval for work to be carried out at unspecified locations anywhere in New Zealand	"*How can ERMA (or anyone) give permission for this when it's not known where these sites will be located, and there have been no safety and risk studies conducted at these locations?*" [10428, Dr Susanna Lyle] "*Federated Farmers is concerned that the exact locations of the proposed facilities have not been identified, and the affected landowners/communities have not been consulted. We understand that this is a generic application and that AgResearch does not think that it is necessary for it to identify the locations as the risks have been identified, but we disagree. Each region in NZ is unique and has different challenges. Placing all the regions in one generic basket is irresponsible and could lead to distinctive risks being missed and not rectified. This situation would place the region/s and research at risk*." [11254, Federated Farmers of New Zealand]

Issues and concerns	Illustrative quotes
Concern about adequacy of containment controls; compliance with or enforcement of containment controls	"*Once GE farming or tests occur workers have been proven to not follow strict containment practices. As the dangers are invisible workers and even scientists are "slap happy". So regardless of any promise of scientific protocols they mean nothing with year in year out activity in the field and even laboratory.*" [11238, Jarad Bryant] "*Concerns over the ability to design controls to minimise the risks. The purpose of controls is to manage the risks, therefore our inability to identify the risks means we were unable to submit to the level necessary on the proposed controls*." [11280, Sustainable Future] "*It is unlikely that MAF have sufficient staff to supervise and monitor the multiple research units.*" [11362, Barbara Mountier] "*AgResearch has not been rigorous in containment compliance with current and previous GE projects (eg Ruakura cattle). I do not trust the extremely powerful commercial influences herwith involved, to meticulously manage these very large projects (GMC07012, GMD07074, GMD08012, GMF07001).*" [11498, Dr Anne MacLennan]
Belief that containment is sufficient	"*The LSN considers the containment controls required under MAF/ERMA Standard 154.03.06: Containment Standard for Field Testing Farm Animals are adequate to ensure any site used is appropriate to manage any risk.*" [11211, Life Sciences Network]
Concern that the precautionary principle should be applied. Concern that the Minister should have called in the applications	"*The upholding of the precautionary principle is paramount. The burden of proof of physiological and ecological safety must be the responsibility of the applicators/promoters of any dubious technology such as genetic modification.*" [11945, John Whyte]
Belief that there are alternative methods to achieve the research aims	"*The areas of potential benefit that the applicant lists (addressing low fertility rates in dairy cows, disease and parasite resistance, lower methane production, drier faeces, enhanced milk composition and wool-fibre characteristics) can all be achieved through conventional breeding and/or organic production methods.*" [11289, Philippa Jamieson] "*ERMA must take into account any alternative method of achieving the research objective that has fewer adverse effects on health and safety and the environment than the field test. There are other ways to manufacture pharmaceuticals and other ethical uses of biotechnology to benefit New Zealand.*" [11360, Greenpeace New Zealand Inc]
Belief that the benefits are overplayed	"*There is little chance most of these extravagant claims would be realised within acceptable cost effectiveness. (considering financial, social, environmental and other costs).*" [11498, Dr Anne MacLennan] "*GE human proteins and synthetic proteins produced by transgenic animals are likely to differ from the naturally occurring human proteins – safety concerns. On p 6 of GMD08012 it says the "these developments signal that transgenic animals have been validated as a suitable production platform for the production of human...pharmaceuticals". Until complete results of comprehensive clinical trials have been published, this claim cannot be made*." [11232, Soil & Health NZ Inc]

Comments from the Department of Conservation and the Ministry of Agriculture and Forestry

Department of Conservation's comments on the applications

The Department of Conservation's comments are reproduced below, as under the Act, the Environmental Risk Management Authority must have particular regard to the views of the Department of Conservation.

"*The Department does not oppose these applications (GMC07012, GMD07074, GMD08012, and GMF07001) by AgResearch to carry out GM work involving a variety of animals. It is our opinion that these applications have been lodged to merge all of this research facility's GM work under the umbrella of these four approvals (if granted). We are confident that the Authority will take into account all significant risks associated with this agricultural work. The Department could not find any evidence of significant risks to conservation values. Our only concern surrounds the wide range of animals that the applications cover. However we have confidence in the Authority to mitigate these risks within their decision (and any associated controls).*"

Ministry of Agriculture and Forestry's comments on the applications

The Ministry of Agriculture and Forestry's comments are reproduced below because they are the compliance agency for new organism approvals.

Submission Form to ERMA New Zealand for New Organism Applications	
Application Codes:	GMC07012, GMD08012, GMF07001, GMD07074
Applicant Name:	AgResearch Ltd
Application Category:	GMC07012: To import into containment and new organism that is genetically modified, under Section 40 of the Hazardous Substances and New Organisms (HSNO) Act 1996. GMD08012: To develop in containment any genetically modified organism (other than by rapid assessment) under Section 40 of the Hazardous Substances and New Organisms (HSNO) Act 1996. GMF07001: To field test in containment any genetically modified organism (other than by rapid assessment) under Section 40 of the Hazardous Substances and New Organisms (HSNO) Act 1996. GMD07074: To develop in containment outside of a containment structure any genetically modified organism or regeneration of a new organism from biological material under Section 40 with reference to Section 44A of the Hazardous Substances and New Organisms (HSNO) Act 1996.
Application Title:	GMC07012, GMD08012, GMF07001, GMD07074
Purpose:	GMC07012: To gain approval to import organisms with a range of genetic modifications and use or maintain those organisms for

	research, breeding and the production of antigens, biopharmaceuticals, enzymes, hormones and other products with commercial applications for release. GMD08012: To gain approval to develop livestock and laboratory animals in outdoor containment and to maintain those species for research, breeding and production GMF07001: To gain approval to field test in containment, organisms with a range of genetic modifications and maintain these organisms for research, breeding and for the production of products with potential commercial applications. GMD07074: To gain approval to develop livestock species in outdoor containment, maintain those livestock for research, breeding and production, and develop animal cell lines (including human and monkey cell lines), *E.coli*, and yeast for use in the development (genetic modification) of livestock and laboratory animals..
ERMA Applications Contact:	Tereska Kozera
Date:	10 Nov 2008
MAF Response Coordinator:	Elizabeth Phillips
Option to Speak in Support of this Submission:	No
Comments provided by:	Barry Wards

BASIS ON WHICH COMMENT IS PROVIDED

MAF submits these comments for consideration to ERMA New Zealand on the following:

Clarity of information
Adequacy of controls
Suggested additional controls

MAF does not provide comments in this submission on the scientific merit, validity or rationale of purpose of the application. These comments, if deemed necessary, will be provided via a separate submission.

Reference	Comment
Relating to:	**GMC07012 (but applicable to the other applications as well, subject to specific comments for those applications below)**
General	MAF expresses some concern at the very generic nature of this application, particularly the general paucity of information and the open-ended timeframe Also, the statement, "Support any research relevant to its (AgResearch) broad mission" is very generic and extremely broad.
Pg 7, section 2.2 2nd to last para	The applicant has undertaken not to use human or Maori DNA in the transgenic programme. It is not clear how this will be determined for compliance purposes.
Pg 7, section 2.2	The applicant states that research will be undertaken at the Ruakura

Last para	research farm in the short term. MAF suggests that a control be included requiring MAF and ERMA NZ to be advised of any additional research sites prior to that research being undertaken.
Pg 9, section 2.2 Para 5	MAF suggests that a control be included stating that no animals products or waste containing animal tissue (including meat and products containing animal cells) from transgenic animals may leave the containment facility, other than for disposal and that, where possible, those products must be non-viable prior to leaving the containment facility.
Pg 12, section 3.1	Section 3.1 requires unequivocal identification of the organisms to be imported. It is not clear from this section of what species are intended to be imported. The generic nature of the organism description is a concern because of the diversity of species that could potentially be imported under this application and the differing containment conditions that these species may require. In addition, many the species within the Genera listed are CITES species, some being extinct in the wild or critically endangered. Although the applicant has addressed this in section 3.3 (Pg 20), MAF suggests adding a controls specifying that: Animal imports are restricted to non-CITES species. Prior to animals being imported, the applicant present detailed plans on how containment requirements will be met for the specific animal species to be imported.
Pg 12, section 3.1	The applicant has identified that only "non-pathogenic" laboratory strains of *E.coli*, *Saccharomyces* and *Pichia* will be imported. MAF suggests that the importation of these organisms be restricted to "non-infectious" strains, rather than "non-pathogenic".
Pg 16, section 3.3	It is not clear what "DNA modules" are?
Para 6	The applicant has stated that "recombinant technology is based upon the knowledge of the function encoded in the sequence of particular pieces of DNA". While this is correct in an outcome sense, the technology also employs manipulation of DNA for which the function is not known (hence the creation of DNA libraries). The paragraph implies that only DNA for which the function of the sequences used is known will be used in the development of the GM organisms. It is assumed that, by the time the DNA will be introduced into an animal, that DNA will have been fully characterised. Is this the intent of this section? It is not clear how the functional aspects of the constructs will be "extensively validated" in cultured mammalian cells?
Pg 17, Section 3.3 Para 2	What is meant by the "integrity" of the DNA construct?
Pg 17, Section 3.3	It is not clear what is meant by "internationally approved"? Presumably the applicant is referring to methods that have been widely used and proven but this is quite different to tagging them with the

Para 4	phrase "internationally approved". Similarly, the applicant has indicated that the methodology used will be both "standard" and "novel" in that any method may be used. There is a degree of risk associated with granting "carte blanche" approval to develop transgenic animals using unknown biotechnology, particularly where the risks of that methodology have not been assessed. MAF suggests that ERMA put controls in place requiring the applicant to, at a minimum, advise ERMA when such novel methodology has been used to develop GMO animals intended to be imported, prior to that importation occurring, and some risk assessment and/or description of that methodology accompany that advisement.
Pg 19, Section 3.3 Para 13	The nature of recombinant technology is such that it is not always known what the "proven functions" of coding, non-coding or regulatory nucleic acids are. This statement is a little misleading in that it infers that the coding functions of any DNA sequence used in the development of the GMO's will be known. MAF does not believe that this is the case at all.
Pg 19, Section 3.3 Para 4, #1	The "purposes" in section 2 are so broad and all-encompassing that it makes the limitations on protein-encoding genes meaningless. This should be made apparent.
Pg 21, Section 3.3 Para 2	Refer to comment 5. If the species limitations are as listed, then the species will need to be known. MAF reiterates the suggested control in comment 5 and further suggests that ERMA be consulted prior to any application for a Permit to Import species being submitted to MAF.
Pg 24, Section 4.1 Para 2	MAF reiterates that any and all sites and facilities to be used for holding GM organisms need to be notifies to MAF and ERMA prior to the events occurring.
Pg 25, Section 4.1 Para 4	MAF suggests that a control be included requiring the applicant to seek MAF approval on all fencing and containment requirements for animals not currently included under the MAF/ERMA Standard 154.03.06: *Containment Standard for Field Testing Farm Animals*, prior to those animals being imported.
Pg 26, Section 4.1 (i)	The applicant implies that laboratory strains of microorganisms present reduced risks because they are attenuated and genetically debilitated; therefore unable to survive outside of laboratory conditions. MAF does not believe that attenuation is necessarily assumed because they are laboratory strains, that genetic modification is necessarily debilitating nor should such characteristics presume that survival outside the laboratory is greatly reduced.
Pg 39, Section 6.2	The applicant states that, "human cells and *E.coli* containing the same genetic modifications have previously been approved by the Authority". If this is the case, then this will limit the scope of imports only to those organisms containing these genetic modifications – remembering that the current application does not list the modifications in the organism description.

Relating to:	GMD08012 (but may relate to the other applications as well)
General	MAF expresses some concern at the very generic nature of this application, particularly around the paucity of information related to the techniques which will be used to genetically modify each line of transgenic animals. While standard techniques will be employed, the applicant is seeking to use any technique, including novel techniques not yet developed. As mentioned earlier, the risks of such techniques are unknown and MAF suggests including controls to assess such risks should such techniques be used.
Pg 42, Section 4.1 Para 3	Unsure what is meant by "non-significant levels" of virally transduced material?
Pg 43, Section 4.1 Para 3	The applicant states that "viable genetically modified products will be permitted to leave the facility for export or to a processing facility or for transfer to other suitable MAF-registered containment facilities". This is in contrast to the statement made on Pg 11 (Section 2.2, para 8), which states that "no products … from transgenic animals containing animal tissues may leave the containment facility other than for disposal". MAF requires clarification of what can or cannot leave the facility, for what purpose and under what authorisation, consistent with the requirements of the appropriate regulatory standards.
Pg 44, Section 4.1 Para 1	MAF suggests that all staff providing care for a particular animal species should have a level of demonstrable experience consistent with animal welfare requirements and any requirements identified in the MAF/ERMA Standard for Zoos, pertaining to specific animal species.
Pg 44, Section 4.1 Para 2	MAF requires that "in all (as opposed to most) cases" no animal may leave the facility without MAF approval.
Pg 47, Section 4.2 Para 1	MAF suggests that specific protocols for transferring transgenic animal species should be developed and submitted to, and approved by, MAF and ERMA prior to the transfer occurring.