IN THE HIGH COURT OF NEW ZEALAND
WELLINGTON REGISTRY

CIV-2008-485-2370

UNDER	the Judicature Amendment Act 1972
AND	
UNDER	the Hazardous Substances and New Organisms Act 1996
BETWEEN	GE FREE NZ IN FOOD AND THE ENVIRONMENT INCORPORATED Plaintiff
AND	ENVIRONMENTAL RISK MANAGEMENT AUTHORITY First Defendant
AND	AGRESEARCH LIMITED Second Defendant

Hearing: 9-10 March 2009

Appearances: T H Bennion and I S Spurdle for the plaintiff
K I Murray and A J Allen for the first defendant
J Smith and S A Mataga for the second defendant

Judgment: 5 June 2009

JUDGMENT OF CLIFFORD J

Solicitors:
Bennion Law, P O Box 25433, Wellington for the plaintiff (tom@bennion.co.nz)
Environmental Risk Management Authority, Wellington for the first defendant
(Counsel: kim@lawchambers.co.nz)
AgResearch, Private Bag 3115, Hamilton for the second defendant,
(Counsel: justin.smith@stoutstreet.co.nz)

CONTENTS

Introduction

[1] The Hazardous Substances and New Organisms Act 1996 (HSNO) controls the importation into New Zealand of new organisms, and their subsequent development, field testing and release. The first defendant, the Environmental Risk Management Authority (ERMA) administers HSNO and considers applications for approvals under HSNO.

[2] In July 2008 the second defendant, AgResearch Limited (AgResearch), made four interrelated applications under HSNO (the Applications) to import into, and develop and field test in, containment a range of new organisms, including genetically modified organisms. Very much in summary, and adopting AgResearch's own words, the Applications are designed to enable AgResearch to carry out a broad genetic engineering research and development programme using "transgenic techniques to support any research relevant to its broad mission to create sustainable wealth for the New Zealand pastoral and biotechnology sectors".

[3] In these judicial review proceedings the plaintiff, GE Free NZ in Food and the Environment Incorporated (GE Free), seeks orders to the effect that ERMA has erred in law by treating the Applications as ones that can be properly considered under HSNO, and an order to stop ERMA taking further steps towards hearing and assessing the Applications. GE Free says simply that the Applications are too generic to constitute proper applications under HSNO.

[4] All parties acknowledge that the Applications seek approval as regards a wider range of new organisms, and a correspondingly broader programme of transgenic research and development, than has previously been considered or granted by ERMA.

Background

[5] AgResearch first approached ERMA about the Applications in September 2007. Since that date there have been ongoing discussions between ERMA and AgResearch on the Applications, including ERMA providing AgResearch with

comments on three substantive drafts of the Applications. Such pre-application consultation between ERMA and a potential applicant is consistent with ERMA's general practice, and no issue was taken in these proceedings with the extent of that contact between ERMA and AgResearch.

[6] During that pre-application consultation ERMA raised with AgResearch on several occasions the breadth of the Applications, in terms of the range of organisms in respect of which the Applications were made, the details of the genetic modifications proposed to those target species organisms, the systems to be used in respect of those proposed genetic modifications and the new organisms that would be used as source material for those proposed genetic modifications. ERMA also commented on the potential implications of the Applications also extending to field testing of genetically modified organisms.

[7] The Applications were formally lodged on 3 July 2008.

[8] ERMA considered that the Applications met the necessary statutory requirements set out in s 40 of HSNO, together with other relevant administrative criteria. On 9 July 2008 the decision was made to formally receive the Applications.

[9] Following formal receipt on 9 July, ERMA initially decided that it would not require AgResearch to provide further information. On 18 July 2008, and after further consideration of the Applications, it was decided that further information should be requested.

[10] On 21 July, ERMA wrote to AgResearch asking for further information relating to the location of the proposed sites, the purpose of the Applications, the proposed containment arrangements and for clarification of the experimental procedures to be used and the beneficial effects anticipated. AgResearch replied on 29 July 2008. It did provide certain additional information – but most of that referred to information already provided. In light of that reply, Mr Atapattu, ERMA's New Organisms Application Manager, considered two alternatives: whether AgResearch did not have the additional information requested, and hence were unable to provide it, or whether they were unwilling to provide it. He

considered the latter to be unlikely as AgResearch, in his view, must have been aware that not providing the further information could diminish the likelihood of the Applications being approved in full or at all. Accordingly, he concluded that AgResearch was unable to provide further information. On that basis, on 5 August and having consulted with ERMA's senior management team, Mr Atapattu decided that ERMA would proceed with the Applications and assess them on the information provided.

[11] The Applications were publicly notified on 7 August 2008.

[12] Submissions were received from 1,724 submitters. A large number, 986, were based on submission templates provided by various environmental advocacy groups, such as GE Free. That is not an unusual situation.

[13] At the present time ERMA is continuing to analyse the issues and concerns raised by submitters. ERMA's evidence was that it was unlikely that process of analysis would be completed before the end of July 2009, with a hearing likely to commence in late August 2009.

The plaintiff's challenge

[14] In its statement of claim, GE Free asks for a declaration "that ERMA's decisions to formally notify the Applications were in error". Its claim therefore appears to focus on s 53 of HSNO. Section 53 requires certain applications to be publicly notified and provides that ERMA may, if it considers that there is likely to be significant public interest, publicly notify other applications.

[15] ERMA and AgResearch responded to those claims, particularly at the hearing, in slightly different but nevertheless broadly similar manners.

[16] ERMA submitted that there was no statutory power susceptible to review being exercised by ERMA under s 53 of the Act. Section 53 involved administrative decisions only. As regards the substance of GE Free's claim, ERMA acknowledged, however, that ERMA did exercise a statutory power under s 52. Section 52 provides

for ERMA to require further information from applicants. The exercise of that power under s 52 involved, in turn, a prior assessment of the Applications under s 40. Therefore, the review GE Free sought could, ERMA acknowledged, be focused on the s 52 power and – by implication – the substantive requirements of s 40. The question ERMA acknowledged as being before this Court was that of the validity of the Applications.

[17] AgResearch argued that there was no statutory power exercised by ERMA which was susceptible to review here. Whilst ERMA may have exercised a statutory power notifying the applications under s 53, AgResearch's submission was that that decision was not the focus of GE Free's case. That is, given the stance taken by submitters, how could GE Free argue that a decision to publicly notify, on the grounds of public interest, was susceptible to challenge? AgResearch was, initially at least, reluctant to accept the approach taken by ERMA.

[18] As the hearing proceeded, however, each of GE Free and AgResearch acknowledged, in line with the position taken by ERMA, that GE Free's challenge was, and was able to be considered by the Court as being, focused on the validity of the Applications and, in an administrative law sense therefore, on the lawfulness of ERMA's actions in accepting the Applications as ones which properly engaged the process of consideration, and potentially approval, provided for by HSNO.

[19] GE Free argued that the failure to identify with any particularity the organisms sought to be modified, the ways in which they might be modified and the range of source material that might be used in that process, together with the open-ended nature of developments and field testings for which approval was sought and the lack of particularity as to the facilities in which those activities might be carried out, meant, in effect, that the risk assessment process called for by HSNO could not properly be carried out. The Applications were simply too generic.

[20] Both ERMA and HSNO acknowledged the breadth of the Applications, and therefore the substantive issues – which might well stand in the way of the approval of the Applications – reflected by GE Free's submissions. At the same time, however, their strong submission was that it would be inappropriate for this Court to

intervene at this point in the process. Decision-making in this area had been entrusted by Parliament to ERMA, an expert body. The decisions called for by the Applications, and the risk assessment process involved, had a heavy scientific content. ERMA's evidence, supported by AgResearch, was that the Applications sufficiently identified their subject matter so as to enable ERMA to carry out the risk assessment process called for. ERMA itself had pointed out to AgResearch the difficulties that the generic nature of the Applications gave rise to, including in its pre-application consultation with AgResearch. ERMA itself had considered the matters the plaintiff now raised and, as the expert scientific body, had determined that the risk assessment called for by HSNO was possible. Whilst there may be unusual cases where an application was so defective as to not be capable of being properly considered by ERMA, and therefore properly to be considered as an invalid application, that was not the case with the Applications. ERMA, the expert decision-making body, should be left to continue the process and to consider the Applications as required under HSNO.

[21] In my judgment, so considered these proceedings raise essentially one issue. That issue is whether, as characterised by Mr Murray for ERMA, the Applications are valid applications – or put more specifically, whether they are so broad and open-ended as to mean that ERMA is not in a position to properly assess the Applications, and therefore should not even embark on that process.

[22] In closing, Mr Bennion commented that GE Free had not, in preparing or presenting its case, provided large amounts of affidavit material, nor focused in any significant way on the affidavits provided by the other parties. Rather, Mr Bennion's submission was that the generic nature of the Applications, and the difficulties they gave rise to as regards a proper consideration of HSNO, could be discerned from a consideration of the terms of the Applications themselves and the scheme of HSNO.

[23] For ERMA and AgResearch the affidavit material was of central significance. That material, combined with those parts of the Applications in which AgResearch addressed the requirements of HSNO, provided a strong evidentiary basis for the proposition that the Applications were properly made and able to be considered

under HSNO, and showed that the plaintiff had not in any way overcome the expert evidence to that effect.

[24] In light of those submissions I will now consider the scheme of HSNO itself, the scope of the Applications, and the affidavit evidence provided to me. I will then consider the central issue raised by this proceeding.

The scheme of HSNO

Purpose and principles

[25] The purpose of HSNO is:

> to protect the environment, and the health and safety of people and communities, by preventing or managing the adverse effects of hazardous substances and new organisms (s 4).

[26] Under s 5, persons exercising functions, powers and duties under HSNO are, to achieve its purpose, required to recognise and provide for two stated principles, namely:

> (a) The safeguarding of the life-supporting capacity of air, water, soil, and eco-systems:
>
> (b) The maintenance and enhancement of the capacity of people and communities to provide for their own economic, social, and cultural wellbeing and for the reasonably foreseeable needs of future generations.

[27] Section 7 prescribes a precautionary approach which again reflects the focus on risk management. Persons exercising functions, powers and duties under the Act:

> … shall take into account the need for caution in managing adverse effects where there is scientific and technical uncertainty about those effects.

[28] The intended effect of these sections was discussed by the Minister of Environment (the Hon. Simon Upton) in moving the Bill (as reported from the Select Committee) for its second reading ((16 April 1996) 554 NZPD 11,899):

> This Bill is all about managing the risks to human health, and the wider environment of hazardous substances and new organisms. The management

> of risks is not a science; it is an art. It involves making value judgments on the basis of technical information that is frequently incomplete. At bottom it involves judgments about just how risk averse we are. That cannot be defined on the face of the statute. All we can do is develop institutions, processes, and guiding principles that enable us to manage risk.
>
> … [W]e have, in promoting legislation like this, implicitly signalled the view that there is a minimum level of risk aversion in the community that means we do not want to expose ourselves to an unlimited range of risks and that sentiment is best captured through a regulatory system that imposes a uniform standard of acceptable risks.

[29] As to ERMA's role, the Minister commented (in relation to whether there should be an appeal *de novo*):

> ERMA, as an expert body, is likely to be as good as, or better than, any other body or person in deciding on the merits, the facts, of a particular application.

[30] The Minister continued:

> The [select] committee's conclusion was that under the Bill as currently drafted, much of the judgment to be exercised by the Environmental Risk Management Authority will be predetermined by regulation. "The regulations are developed through a public consultation process, and all interested parties can make their views known. The authority will then assess a substance or organism and, in the light of the regulations, make a decision. So the likelihood of the authority making a mistake in terms of the facts of a particular approval is very remote. It is more likely that any mistake will be the result of inadequate or inaccurate information being provided by the application. [Section 62(2)(a)] provides for reassessment on the basis of new information. This will enable such mistakes to be corrected".
>
> I think the select committee was correct in that.

[31] The Chairman of the Select Committee, Mr Nick Smith, commented (at 11,907):

> … I think it is quite proper that Parliament expects from the new Environmental Risk Management Authority a degree of rigour and a degree of careful assessment of those applications—both for new organisms and for genetically modified organisms, as well as for chemicals—that ensures both consistency and a full degree of analysis of the effects of those chemicals. That is why the select committee has amended the Bill and has introduced a specific clause that states that the Environmental Risk Management Authority is required to apply some rigour to the process. Neither this Parliament nor the community should want an airy-fairy authority that will make decisions on the whim of the politics of the day. We want an authority that will base its decisions on rigour and science.

Approvals required

[32] With the purpose of HSNO in mind, and as relevant, no "new organism" may be "imported, developed, field tested, or released" except in accordance with an approval issued under the Act (s 25(1)). A "new organism" includes a genetically modified organism (ss 2(1) and 2A).

[33] The terms import, release, containment, and field test are all defined:

a) Import has the same meaning as in s 2(1) of the Biosecurity Act 1993, namely to bring within New Zealand territory from outside New Zealand territory.

b) Release means to allow an organism to move within New Zealand free of any restrictions other than those imposed in accordance with the Biosecurity Act or the Conservation Act 1987.

c) Containment means restricting an organism to a secure location or facility to prevent escape and includes, in respect of genetically modified organisms, field testing and large scale fermentation.

d) Field test means, in relation to an organism, the carrying on of trials on the effects of the organism under conditions similar to those of the environment into which the organism is likely to be released, but from which the organism, or any heritable material arising from it, could be retrieved or destroyed at the end of the trial.

[34] Section 40(1) requires every person intending to import into, or develop or field test in, containment any new organism to apply to ERMA for approval.

Information to be provided

[35] All applications under s 40(1) are required to be in the approved form and to include (s 40(2):

a) any prescribed information, including, for example, and as not specified elsewhere, identification and assessment of risks, costs, benefits and other impacts, information on New Zealand's international obligations that may be relevant to the application and assessment of possible effects on the relationship of Māori and their taonga: forms 2, 3 and 4 of the Hazardous Substances and New Organisms (New Organisms Forms and Information Requirements) Regulations 1998 (NOFIR Regulations).[1]

b) information derived from consideration of the organism by governments of prescribed states or countries; and

c) information about the containment system for the organism.

[36] Where, as here, a s 40 application is to develop a genetically modified organism in containment, the application must also include (s 40(2)(a)):

a) the identification of the organism;

b) the description of the project and the experimental procedures to be used;

c) the details of the biological material to be used;

d) the expression of foreign nucleic acid material; and

e) all the possible adverse effects of the organism on the environment.

[37] Where an application is to field test a genetically modified organism, the application must also include (s 40(2)(b)):

a) the identification of the organism;

---

[1] The NOFIR Regulations, and in particular reg 9 in combination with the notes to the forms, require information that is directed to matters, as described in [38] and following, to be considered by ERMA.

b) the purposes of the field testing;

c) the genetic modifications of the organism to be tested;

d) the nature and method of field trials and the experimental procedures to be used; and

e) all possible adverse effects of the organism on the environment.

Matters to be considered

[38] Section 45(1) provides the framework for consideration by the Authority of applications under s 40. ERMA may approve an application if:

a) the application is for one of the purposes specified in s 39(1), including the development or field testing of any new organism; and

b) after taking into account all the effects of the organism and any inseparable organism, ERMA concludes that the beneficial effects of having the organism in containment outweigh the adverse effects of the organism and any inseparable organism; and

c) ERMA is satisfied that the organism can be adequately contained.

[39] If not satisfied on those matters, ERMA is to decline the application.

[40] In the case of all applications under s 40, s 45(4) requires ERMA, when considering adverse effects, to take into account not only the adverse effects (if any) of having the organism in containment, but also:

a) the probability that the organism may escape, after considering all the controls to which the organism would be subject if the application were approved; and

b) the effects of the organism, if the organism were to escape.

[41] Section 45(1)(a)(ii) requires ERMA, when considering effects, to take into account:

a) In the case of all applications to develop a new organism in containment:

i) the ability of the organism to establish an undesirable self-sustaining population; and

ii) the ease with which the organism could be eradicated if it established an undesirable self-sustaining population.

b) In the case of applications to develop a new organism in containment by genetic modification:

i) the matters specified at above (a); and

ii) as specified in regulations promulgated under s 41 identifying the procedures and methods for assessing the probability of adverse effects occurring from a genetic modification, specifying the probability that adverse effects will occur from specified development procedures and defining low risk genetic modifications (the Hazardous Substances and New Organisms (Low-Risk Genetic Modification) Regulations 2003).

c) In the case of applications to import into containment, or field test:

i) the matters specified at above (a); and

ii) the ability of the organism to escape from containment.

[42] In the case of applications to develop in containment but not in a containment structure (i.e. in outdoor containment), or to field test, a genetically modified organism, s 44A requires ERMA to take into account:

a) any adverse effects of developing or field testing the organism on:

i) human health and safety; and

ii) the environment, in particular ecosystems and their constituent parts;

b) any alternative method of achieving the research objective that has fewer adverse effects on the matters referred to in paragraph (a) than the development or field test; and

c) any effects resulting from the transfer of any genetic elements to other organisms in or around the site of the development or field test.

Controls required

[43] In terms of controls, and directly relevant to the question of the required assessment of the probability that an organism may escape, s 45(2) requires all approvals under s 45 to include controls that provide for each of the matters stipulated in Schedule 3 (and provides that approvals may include other controls in order to give effect to the purpose of HSNO). The matters stipulated in Schedule 3 are extensive, and include:

a) Various requirements to limit the likelihood of any accidental release of any organism or any viable genetic material;

b) Details of, and security requirements concerning, access to the facility to exclude unauthorised people from the facility;

c) Monitoring requirements to establish the presence of other organisms, phytosanitary requirements and requirements to secure the facility and

openings against likely unwanted organisms, to exclude other organisms from the facility and to control undesirable and unwanted organisms within the facility;

d) Various requirements to prevent unintended release of the organism by experimenters working with the organism;

e) Requirements to control the effects of any accidental release or escape of an organism;

f) Inspection and monitoring requirements for containment facilities; and

g) Potentially, the qualifications required of the person responsible for implementing the controls imposed and the provision of the management plan.

[44] Section 45A provides for additional controls where approval is sought to develop a genetically modified organism in outdoor containment or to field test a genetically modified organism. Such approvals:

a) must include controls to ensure that after the end of the development or field test the organism and any heritable material from the organism is removed or controlled; and

b) may include controls to ensure that after the end of the development or field test, and after heritable material is removed or destroyed, some or all of the genetic elements remaining from the organism are removed or destroyed.

[45] In that context, “destroyed” is defined to include leaving genetic elements to break down or become inactive at the site of the development or field test.

Other provisions

[46] ERMA has produced application forms (under s 11(1)(fa) of HSNO), with associated user guides, providing direction for applicants in terms of providing the information required to be in an application.

[47] In addition, the Hazardous Substances and New Organisms (Methodology) Order 1998 establishes a methodology to be used by ERMA in making decisions in relation to applications. Clauses 29-33 of the Schedule deal with uncertainty in applications.

Summary

[48] The information required to enable ERMA to consider and grant an application under s 40 to import, develop and field test genetically modified organisms can therefore be summarised as comprising essentially:

a) the identification of the organisms to be imported, developed or field tested (s 40(2));

b) the identification of the procedures whereby imported organisms are to be genetically modified, and the description of the source genetic material to be used for that purpose (s 40(2)(a));

c) the proposed containment system, the nature and purpose of the field tests involved (s 40(2)(b)) and information to enable ERMA to assess and specify the necessary controls; and

d) all the possible beneficial effects of having the organism in containment and all of the adverse effects of the organism on the environment.

[49] Identification of the organism will include information from prescribed states and countries' consideration of the organism (s 40(2)). That and adverse effects under (d) are what will enable ERMA to assess the effects of the organism if it were

to escape (ss 40(2)(a)(v) and (b)(v); 44A(2); 45(4)) – including its ability to establish a self-sustaining population and the ease of eradicating such (ss 37; 45(1)(a)(ii)). Identification of the organism, the containment systems, the nature of the field tests and information as to the necessary controls will enable ERMA to assess the probability that the organism will escape (ss 44(b); 45(4)). The nature and purpose of the field and containment system, the controls and the assessed adverse effects will allow ERMA to consider whether there is an alternative method of achieving the purpose with fewer adverse effects (s 44A(2)(b)).

[50] Together, this information is designed to enable ERMA to assess whether the benefits of having the organism in containment outweigh the adverse effects of the organism and any inseparable organism (s 45(1)(a)(ii)), and to be satisfied as to whether the organism can be adequately contained (s 45(1)(a)(iii)).

The scope of the Applications

Overview

[51] AgResearch applied:

a) to import into containment new genetically modified organisms comprising specified livestock, laboratory animals and other organisms (the Import Application – GMC07012);

b) to further develop (i.e. genetically modify) in a containment structure those specified livestock, laboratory animals and other organisms (the Indoor Development Application – GMD08012);

c) to further develop (i.e. genetically modify) in outdoor containment those specified livestock – but not the laboratory animals or other organisms (the Outdoor Development Application – GMD07074); and

d) to field test the specified (genetically modified) livestock (the Field Test Application – GMF07001).

[52] To set out the scope of the Applications I can do no better than to refer to the Application Summary prepared by AgResearch. AgResearch introduced each separate Application with a version of this summary, modified for the particular Application. I quote from the version used to introduce the Import Application:

> **Application summary prepared by AgResearch Limited – Corporate Office**
>
> AgResearch seeks approval under this application 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.
>
> AgResearch has research programmes under existing transgenic cattle development and field test approvals (GMF89009, GMD02028).
>
> This application is one of four concurrent applications (the other three are GMD07012 [sic], GMD07074 and GMF07001) under which AgResearch seeks to continue and extend the research programme to allow AgResearch to use transgenic techniques to support any research relevant to its broad Mission to create sustainable wealth for the New Zealand pastoral and biotechnology sectors. AgResearch believes that will include:
>
> 1. **Products with commercial applications:** Undertake research and maintain and breed livestock for production of:
>
>   - therapeutic proteins
>   - proteins for use as diagnostics for human and animal disease
>   - other products derived from livestock with commercial applications
>
> 2. **Enhancement of livestock traits:** Maintain and breed livestock for research into enhancement of traits of value in livestock including productivity, welfare and sustainability.
>
> 3. **Animal models of human gene function and physiology:** Maintain and breed livestock for use in research as models for human gene function and physiology.
>
> 4. **Transgenic techniques; gene function:** Maintain and breed livestock for research into transgenic techniques and gene function to support the above purposes and, if discoveries of general application are made in the course of such research, for further research into such discoveries.
>
> …
>
> **Relationship between approvals**
>
> AgResearch is submitting four applications with common or overlapping organism descriptions and controls. This application should be read with the other applications. All of the applications are for approval of activities in containment and together they will allow AgResearch to do the following with organisms fitting the organism description in this application:

- GMC07012 (this application): Import into containment livestock and laboratory animal species (live animals, sperm, embryos – importation of live animals into containment will be rare). Maintain those animals for research, breeding and production. Import animal cell-lines (including human and monkey cell-lines) and *E. coli* for use in the development (genetically modification) of livestock and small animals under GMD07012 [sic] and GMD07074.

- GMD08012: Develop livestock and laboratory animals in indoor containment. Maintain those species for research, breeding and production. Develop animal cell-lines (including human and monkey cell-lines), *E. coli* and yeast for use in the genetic modification of livestock and laboratory animals.

- GMD07074, this application: Develop livestock species in outdoor containment. Maintain those livestock for research, breeding and production.

- GMF07001: Field test livestock in outdoor containment. Maintain those livestock for research, breeding and production.

[53] The following table, adapted from the Import Application, specifies the organisms involved:

Unequivocal identification of the organism(s) to be imported		
Taxonomic classification	**Common name(s), if any**	**Type of organism (e.g. bacterium, virus, fungus, plant, animal, animal cell)**
Livestock:		
Bos	Cattle	Animals, animal cells, embryos, sperm, ova
Bubalus	Buffalo	Animals, animal cells, embryos, sperm, ova
Capra	Goat	Animals, animal cells, embryos, sperm, ova
Ovis	Sheep	Animals, animal cells, embryos, sperm, ova
Sus	Pig	Animals, animal cells, embryos, sperm, ova
Cervus	Deer	Animals, animal cells, embryos, sperm, ova
Lama/Vicugna	Llama, alpaca	Animals, animal cells, embryos, sperm, ova
Equus	Horse	Animals, animal cells, embryos, sperm, ova
Laboratory animals:		
Rattus (excluding Rattus exulans)	Rat (excluding kiore)	Animals, animal cells, embryos, sperm, ova
Mus	Mouse	Animals, animal cells, embryos, sperm, ova
Oryctolagus	Rabbit	Animals, animal cells, embryos, sperm, ova
Trichosurus	Possum	Animal cells, embryos, sperm, ova
Gallus	Chicken	Animals, animal cells, embryos, sperm, ova
Cricetulus, Cricetus, Mesocricetus	Hamster	Animal cells, embryos, sperm, ova.
Cavia	Guinea pig	Animals, animal cells, embryos, sperm, ova.

Other organisms:		
Chlorocebus	Monkey	Animal cells
Homo sapiens	Human	Animal cells (excluding gametes and embryonic stem cells)
Escherichia coli (non-pathogenic laboratory strains only)		Bacterium
Saccharomyces, Pichia (non-pathogenic laboratory strains only)		Fungus

[54] Ms Bleakly, for GE Free, in one of her two affidavits provided a list of some 75 species included in the nine livestock genera the subject of the Applications. That list includes a significant number of species not currently present in New Zealand in any form. Each of the Applications, however, proposes a further inclusion to the organism description "for the Authority's consideration". That description would read:

> This approval applies only to those species
>
> (a) present in New Zealand at the time of granting this approval or
>
> (b) for which there is, at the time the work commences, an existing new organism approval for importation of the host organism species.

[55] The Outdoor Development Application contains the following table listing the species currently present in New Zealand and by reference to which, therefore, that "proposed" inclusion would operate (pending any further new organism approval):

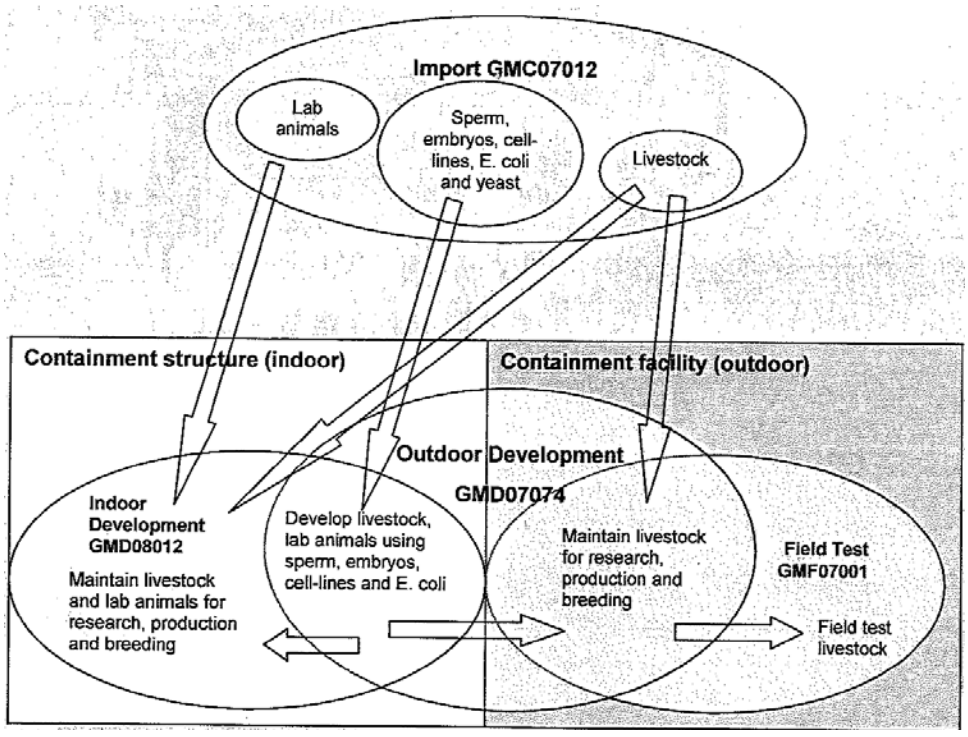
Genus	**Species present in New Zealand**	**Common name(s)**
Bos	Bos taurus Linnaeus, 1758 Bos primigenius	Domestic cattle Zebu
Bubalus	Bubalus bubalis	Asian Water Buffalo
Capra	Capra hircus	Domestic goat
Ovis	Ovis aries	Sheep
Sus	Sus scrofa	Pig
Cervus	Cervus elaphus Cervus nippon Cervus canadensis Cervus unicolor Cervus timorensis	Red deer Sika Wapiti Sambar Javan rusa deer

Lama/Vicugna	Lama Glama Lama/Vicugna pacos	Llama Alpaca
Equus	Equus caballus Equus asinus	Domesticated horse Donkey

[56] The effect of those provisions of the Applications would appear to be that, whilst AgResearch was formally applying for approval at the genus level for the nominated livestock species, it anticipated problems with obtaining such an approval and therefore invites ERMA to narrow the approval by reference to the species listed in the table.

[57] In the Application Summary, AgResearch goes on to describe the Applications in the following way:

> The applications should be read together as an application for an integrated set of approvals covering a single set of research activities. The relationships between them are set out in the diagram below.



> AgResearch's intention in making the suite of applications is that AgResearch has all possible approvals needed under the HSNO Act for research, breeding and production using livestock in containment. This will ensure that AgResearch has the flexibility to:
>
> - Undertake research or commercial production with transgenic livestock lines which AgResearch has developed itself or with lines developed by other parties and imported.

- Undertake development and maintain livestock in both indoor containment and outdoor containment. For example transgenic goats are provided for in both the indoor and outdoor applications as it is possible that commercial herds will be required to be kept in-doors to meet pharmaceutical regulatory requirements but research herds may be kept in outdoor containment.
- Undertake activities in outdoor containment regardless of whether they are developments or field tests. The boundaries of the field test definition have not been fully tested. However, AgResearch expects field tests may occur if AgResearch is evaluating the effects of livestock in anticipation of a future release approval or if AgResearch is undertaking comparative trials of the effects of transgenic and conventional animals. With both approvals in place, both AgResearch and ERMA can be assured that whatever the boundaries, the activity will be approved under one approval or the other.

The approval sought under this application will also authorise AgResearch to import small animals, cell-lines and microorganisms that support the livestock activities. Cell lines from livestock and small animals and from humans and monkeys will be used for evaluation of DNA construct and experimental strategies. *E. coli* and yeast will be used for DNA construct development. Rates, mice, hamsters, guinea pigs, rabbits, possums will be used as research models for all livestock activities.

[58] The Applications rely on AgResearch's existing approved containment facilities at Ruakura and the possibility of further facilities at as yet unspecified locations, to be built in accordance with applicable regulatory requirements.

[59] The approvals sought under the Applications are for an unlimited duration.

[60] The Application Summary makes it clear, therefore, that the Applications, if approved, would allow AgResearch first to import into containment specified organism types of the specified livestock, laboratory animals and other organisms, already genetically modified in ways not previously present in New Zealand. Once imported, AgResearch could further genetically modify those organisms whilst in indoor containment. Finally, AgResearch could further genetically modify in outdoor containment, and field test, the specified livestock.

[61] AgResearch could use any technique available, now or in the future, to effect such genetic modification and could do so using genetic material from the specified livestock, small animals, humans and monkeys, *E. coli* and yeast organisms as specified in the Applications. Each of those approvals could be implemented at Ruakura, or at yet to be located facilities.

[62] An analysis of the terms of the individual Applications, by reference to various elements of the summary of the requirements of the statutory scheme set out at [48], confirms the scope of the approvals sought. As the fact of the breadth of the Applications was accepted by all parties, I do not think it is necessary to set out that analysis in great detail. It is however helpful to note some key aspects of the individual applications.

The Import Application

[63] In response to the need to provide the "unequivocal identification" of the organisms to be imported, the Import Application provides the table reproduced at [53]. It goes on to state:

> **Genus level organism description**
> The organisms described in this application (other than *E. coli*) are at the genus taxonomic level. This is because the application involves both basic and applied research that necessarily requires exploration of a full range of animal candidates. While AgResearch may not be involved with all of the animals at all stages, the pace of global research and development using different transgenic animals is rapid. To keep up with global research directions and to take advantage of commercial opportunities, AgResearch needs to have regulatory approvals in place for a broad range of animal candidates. This import into containment application includes whole genetically modified animals from the genera listed. It does not cover the import of unmodified animals as these require separate ERMA approvals.
>
> A range of host organisms are required to meet the needs for the different intended applications of transgenic technology in the development of transgenic animals. This reflects the broad scope of the application which encompasses not only the use of transgenic animals for production of recombinant proteins but also the development of new animal models that can be used to study human disease. The current range of transgenic animals used in biomedical research and for producing bioproducts [globally] is set out in Appendix III.

[64] To provide the unique names for the new organisms to be imported, which are to be entered into the public register and "should clearly identify the species and strains and genetic modifications" (ERMA Application Form ER-AN-02G 11/02, Form 2G, at 3.2), AgResearch lists each of the genera, and then in each case (with minor modification for *Cervus* (goats) and *Lama/Vicugna* (llama/alpaca) adds the following description:

> genetically modified with additional gene sequences derived from animals, microorganisms, viruses, plants or synthetic sequences and nucleic acids that are either stably integrated or extra-chromosomally maintained.

[65] In answer to the question "How were the new organisms developed" AgResearch states:

> Because of the generic nature and duration of the application, it is not possible to identify at the time of the application which techniques will be used to genetically modify each line of transgenic animals which may be imported if the approval sought is granted. AgResearch therefore seeks approval to import organism [sic] modified using any technique available.

[66] The reference to "any technique available" is very clear. AgResearch does provide a description of likely techniques, without limiting that very general statement. AgResearch also provides a description of the types and sources of additional genetic material and non-vector nucleic acids, and provides certain exclusions – including "DNA from Māori" and "DNA from native flora and fauna", and certain effects based and qualitatively described material, for example modifications that would be "toxic". How that qualitative assessment would be made by AgResearch, and why that judgment should be left to AgResearch – given the scheme of HSNO – was not specifically addressed.

[67] The Import Application described the characteristics of the organisms to be imported. In terms of the livestock species, that description was as follows:

> Imports may also include genetically modified whole animals. In vivo studies will involve common domesticated animals used widely for research and livestock farming purposes. The unmodified animal characteristics are well understood with most of candidate animals having a long history of domestication. The genetic modifications are not expected to change the behavioural characteristics of the animals or increase the potential for these animals to harbour new pests and diseases or otherwise cause harm to humans or adversely affect the environment in light of the restrictions in the organism description and controls. In all respects the genetically modified animals are not expected to present any management challenges over and above those normally experienced with unmodified counterpart animals. AgResearch is not aware of any literature suggesting that individual species within the genus classifications will pose any unusual or unknown containment issues.

The Indoor Development Application

[68] AgResearch summarised the Indoor Development Application as follows:

AgResearch seeks approval under this application to:

- Develop (genetically modify) within a containment structure livestock and laboratory animals from 18 genera (livestock and laboratory animals) with a range of genetic modifications and maintain those animals for research, breeding and for the production of antigens, biopharmaceuticals, enzymes, hormones and other animal products with commercial applications for release.

- Develop within a containment structure animal cell-lines (from the above genera and from humans and monkeys), *E. coli* and yeast for use in the development of livestock and laboratory animals as described above.

[69] AgResearch fully acknowledges the width of the Indoor Development Application in terms of the organisms to be developed, relative to the "generic" application considered in its existing approval GMD02028 (as upheld in *Mothers Against Genetic Engineering Incorporated v The Minister for the Environment & Ors* HC AK CIV 2003-404-673 7 July 2003 (the *MAdGE* case)):

[70] In answer to the question, "How will the new organisms be developed?" AgResearch, as in the Import Application, sought approval for, in effect, all existing or future techniques. It commented:

> AgResearch believes that specificity about the development methodology is not necessary for ERMA to assess the potential adverse effects of the activities for which approval is sought and the efficacy of controls to mitigate those effects because in all cases:
>
> - Genetic modification steps involving cell-lines and microorganisms will be undertaken in indoor containment under strictly controlled laboratory conditions using established safety protocols.
>
> - The developments will comply with all or most of the requirements of the HSNO (Low Risk Genetic Modification) Regulations 2003 (specific risk issues relating to the use of viral vectors, which are outside the requirements of the Regulations are discussed in detail elsewhere in this application).
>
> - The end product of modification process will be livestock and laboratory animals. The modification techniques used will not materially influence the risks associated with the organism (with the possible exception of risks associated with the use of viral vectors, which are discussed in detail in this application).

[71] As to the proposed containment system, AgResearch states that all research activities will be undertaken in containment facilities registered in accordance with s 39 of the Biosecurity Act and which "may be situated in different locations in New

Zealand at AgResearch campuses". All containment facilities will conform to the operational standards required by MAF and ERMA and will "generally follow the procedures used in the AgResearch containment facilities located at Ruakura as described".

[72] The Indoor Development Application records that possible pathways by which the organism may escape from containment could include infection with viral stock, inadvertent or deliberate removal (sabotage) of biological materials, escape of host cell or tissue cultures and escape of animals. It refers to the likelihood of these events, and controls and contingency plans to manage these risks.

[73] In terms of the ability of an organism to establish self-sustaining population (ss 37; 45(1)(a)(ii)) AgResearch comments:

> AgResearch believes that it is highly improbable that transgenic livestock or other GMOs will escape from indoor containment and establish a self-sustaining population (see section 4.1 and 4.2 above and discussion below). Application GMD07074 discusses this issue in relation to livestock in some detail and risk elements identified in that discussion will not generally be discussed further than being identified again.
>
> …
>
> In the unlikely event that the full escape pathway is completed it would be unlikely that the animals would be able to be recovered or eradicated in the case of mice, rats, possums and rabbits but chickens are likely to be more recoverable. Hamsters and guinea pigs would not be likely to survive for long in the wild.
>
> …

[74] After identifying potential adverse effects on the environment – such as "degradation of natural environment through release or escape of GM animal", "development of new human diseases" and "effects on whakapapa and mauri" in terms of modification inserting human genes into livestock – the Indoor Development Application states:

> In AgResearch's experience with operating containment facilities to date there has not been any instance of genetically modified livestock or laboratory animals being removed or escaping from any Ruakura facility. It is very unlikely if not improbable that this will occur in the future without deliberate human intervention. There is a small increased risk while moving animals between facilities, but a series of events would have to all occur at

> once and contingency plans be effectively comprised, along with a passage of time for any noticeable adverse effect to be detrimental to the environment.
>
> Maintaining animals in indoor containment will largely eliminate any risk to the natural environment.

[75] The Indoor Development Application, as for each of the Applications, contains risk assessment assertions by AgResearch that are not susceptible to assessment by this Court on judicial review.

[76] Concluding on unanticipated adverse effects, AgResearch comments:

> **Analysis**
>
> The breadth of the modifications permitted by the organism description in this application creates uncertainties regarding the likelihood and magnitude of unanticipated adverse effects. This issue was discussed in section 4.4 of GMD02028.
>
> Significant limitations are imposed on the probability and magnitude of the impacts of unanticipated adverse effects by choice of host organism. Effects may range from no observable effect, to a range of morphological, physiological, or behavioural abnormalities, to premature death of animals. In most cases the magnitude of effect is expected to be minimal as only the modified animal is affected. Further, most adverse effects of significance will be identified in preliminary stages of research in vitro or with laboratory animals, which occur in indoor containment.
>
> **Evaluation**
>
> The extent to which modified animals will result in unanticipated effects to the environment, human health, society, Māori and the economy is further limited by the fact that the modified livestock are in indoor containment, and the pathways out of containment are finite and managed under the containment controls. The likelihood and magnitude are also limited by numbers of modified animals in each initially developed line (likely to be no more than 50). Developed lines that move into production phases are likely to have good knowledge around any effects by the time they reach the stage needing an increase in numbers.

[77] Overall, on benefits and risks, AgResearch concluded:

> The genetic modifications and activities proposed under this application (and the concurrent applications) while broader than those approved by the Authority under AgResearch's previous applications, are nevertheless of the same nature. The host organisms are common livestock species and all activities will be in registered containment facilities. Known risks are excluded in the organism description. AgResearch has not identified any unique or novel issues in this application that have not been considered by the Authority in the past. Even taking account of the breadth of the modifications allowed, ERMA can reasonably conclude that the probability of any adverse effect on the environment or human health which is more

> than minimal is highly unlikely. Adverse social and economic effects are mitigated by the exclusion of animal products from the food chain.

The Outdoor Development Application:

[78] This Application is broadly similar to the Indoor Development Application. Outdoor development approval was sought as the research programme "involves development and proof of concept work using large animals such as cattle and sheep … not amenable to indoor containment". In words specific to this Application, AgResearch explained the rationale for the generic approach:

> The application is generic in that it seeks a long term approval for work in a range of species and a range of genetic modifications. The judicial review of a previous generic application established that ERMA has the jurisdiction to assess applications on a generic basis. AgResearch wishes to avoid the expense and time involved in making applications which raise identical or very similar issues on a case by case basis. It does, however, raise issues for ERMA as to the assessment of risk on a generic basis. AgResearch has endeavoured to address these in the information provided in the application and in the methodology used in risk assessment in section 6 (see appendix XIII for discussion of the methodology).

[79] In a similar way to the Indoor Application, the Outdoor Application refers to the proposed location of activities as follows:

> AgResearch currently operates a research farm at Ruakura, near Hamilton, which has a MAF approved animal containment facility in which all animals and animal products involved in genetic modification research are kept. In the short term the research will be undertaken only at this site. However, the existing containment facility is on leased land and is close to residential areas which restricts the ability to expand capacity and means it is unlikely to be the long term site of all research activities. If commercial therapeutic protection production commences, it is likely to be at a separate facility from that which carries out the initial research phases of the program.
>
> For these reasons AgResearch is seeking a non-specific site approval. Other suitable sites around New Zealand may therefore be used at some future time to fulfil the requirements needed for the production of commercial volumes of selected therapeutic proteins or to allow research phases to continue.
>
> …
>
> We acknowledge that the lack of specificity relating to the site raises an issue for ERMA as to whether it can properly assess effects of the activities for which we are seeking approval without knowing where the activities are carried out.

[80] AgResearch essentially argues that approval can nevertheless be given on the basis that all activities would be undertaken within containment facilities operated in accordance with standards and procedures approved by MAF and ERMA, referring to the MAF/ERMA Standard 154.03.06: *Containment Standard for Field Testing Farm Animals*. AgResearch also pointed to its experience to date at Ruakura as supporting the efficacy of its procedures.

[81] The Outdoor Application identifies potential adverse effects for the environment, and evaluates these in substantially similar terms as for the Indoor Development Application (at [74] above). Again, these are risk assessment assertions not susceptible to assessment by the Court on review. AgResearch reaches a materially identical conclusion on unanticipated adverse effects and overall risks and benefits (see [76] and [77]).

The Field Test Application

[82] AgResearch commented on the scope of the Field Test Application:

> This application is for a generic approval (i.e. approval for any field test of organisms complying with the organism description for the purposes set out in this application) of unlimited duration. It is therefore not possible at the time of application to specify all the details of each field test which may be carried on under this approval (including the effects tested, the location or duration).
>
> AgResearch submits that to comply with the requirements of the HSNO Act the description of the field test must be sufficient for three purposes:
>
> - To enable ERMA to determine what information, if any, ERMA might need to properly assess the application;
> - To enable ERMA (and submitters) to assess adverse effects and benefits, accepting that ERMA may request and the applicant may supply additional information for this purpose;
> - If an approval is granted, to provide a reference point so ERMA/MAF might know with certainty what it is that has been granted and therefore be able to ascertain whether the applicant is acting within the scope of the approval granted.

[83] AgResearch submitted that any field test carried out in containment with the proposed controls would meet those requirements because, essentially and as for the

Outdoor Containment Application, field tests would be conducted in accordance with applicable standards, again emphasising AgResearch's experience to date with its facility at Ruakura.

[84] The scope of the Applications is obvious.

The Evidence

GE Free

[85] For GE Free, affidavits were provided by its president, Ms Claire Bleakley, by a Dr Jessica Hutchings and by a Mr Peter Wills.

[86] Ms Bleakley provided two affidavits.

[87] In her first affidavit she set out GE Free's background and objective. She then recorded GE Free's concerns that:

a) the Applications seek permanent authority to undertake a wide range of genetic modifications at unspecified sites in New Zealand;

b) the Applications either entirely lack information or provide information that is so deficient that meaningful submissions on them are impossible and public input is essentially stymied; and

c) that even specialist organisations such as GE Free had been unable to discern all possible situations and risks that might arise.

[88] Ms Bleakley said the Applications were so generic and confusing and provided so little information that members of GE Free and the public do not know what they need or want to submit on.

[89] In her second affidavit, Ms Bleakley summarised GE Free's analysis of, and experience with, the process to date whereby submissions had been made to ERMA on the Applications. She noted that of the approximately 1,760 submissions that had

been filed with ERMA, 70% of them contained an explicit statement or statements that the Applications are too vague, or lack sufficient information for the submitter to make a meaningful submission, and noted that a range of other submissions made similar points. She further commented on certain matters that had been discussed between ERMA and AgResearch which, in her view, supported GE Free's concerns.

[90] More particularly, Ms Bleakley noted:

a) the open-ended nature of the Applications as regards the methods of modification ("any technique available"). By reference to earlier discussions, she noted that this would include new, more risky and as yet not invented methods of genetic modification, and commented it was hard to see how ERMA might begin to assess the risk of yet unknown modification mechanisms; and

b) that the Application in effect sought approval for unidentified sites throughout New Zealand.

[91] Dr Hutchings is a lecturer in Māori resource management at Victoria University. Her particular concern was that, as the Applications do not specify any sites for development, it is impossible for Māori submitters to make meaningful submissions. Similarly, her concerns were also with the open-ended nature of the organisms to be modified, the methods and types of modification, and the influence on the question of the sites that might be used.

[92] Dr Hutchings said that what was being sought was something akin to a national protocol.

[93] Dr Wills is an Associate Professor in the Department of Physics at Auckland University. His perspective was that there was much we do not know at even a basic level about genetic changes and the outcomes of genetic modification. In asking for permission for genes to be inserted into any species derived from any one of nine genera, AgResearch provided an application to which no meaningful response could

be given and which, in turn, ERMA could not assess in the manner required under HSNO.

ERMA

[94] For ERMA, affidavit evidence was provided by Mr Asela Atapattu, ERMA's New Organisms Application Manager, and Dr Kirsty Allen, ERMA's Senior Environmental Risk Adviser.

[95] Mr Atapattu's affidavit explained the process adopted by ERMA. He emphasised on several occasions how ERMA had responded to the obviously generic nature of the Applications, and had sought or suggested that AgResearch submit further information. He noted, in particular, that AgResearch did not provide significant new information in response to ERMA's request for such information after the Applications had been filed. In his words "AgResearch was taking an informed risk that the information provided may be insufficient for [ERMA] to approve the applications".

[96] In terms of GE Free's core submission as to the difficulty for ERMA of assessing risk associated with the Applications, Mr Atapattu's view was that ERMA has a number of mechanisms available to mitigate risk, such as constraining the organism description or the proposed activities, including the methods for developing a genetically modified organism and by way of prescribing additional controls. The issue of uncertainty was one which ERMA itself would consider in making its decision.

[97] In her affidavit, Dr Allen described why it was considered that the applications contained sufficient information to fulfil the requirements under HSNO to be formally received and publicly notified. Given ERMA and AgResearch's reliance on Dr Allen's assessment, I will set out the contents of Dr Allen's affidavit in some detail.

[98] Dr Allen first considered, in the context of the Import and Development Applications, information provided relating to:

a) the containment system;

b) the identification of the organism;

c) the description of the project;

d) the experimental procedures to be used, the biological material to be used and the expression of foreign nucleic acid material; and

e) all the possible adverse effects of the environment.

[99] She then discussed, in the context of the Field Test Application:

a) the containment system, the nature and method of field trials and the experimental procedures to be used;

b) the identification of the organism;

c) the purposes of the field testing;

d) the genetic modifications of the organism to be tested; and

e) all the possible adverse effects of the organism on the environment.

[100] I will summarise Dr Allen's evidence on these matters in respect of first, the broad description of the project, and secondly, the four essential categories of information required under HSNO as I have identified above (at [48]). I then set out her overall conclusion.

- The project broadly

[101] As to the project broadly, Dr Allen quoted from the Import and Development Applications where they state:

> The purposes for which AgResearch will utilise the approval 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. AgResearch believes these purposes will include:
>
> 1. Products with commercial applications …
> 2. Enhancement of livestock traits …
> 3. Animal models of human gene function and physiology …
> 4. Transgenic techniques, gene function … (emphasis excluded)

[102] Dr Allen then noted that approvals of unlimited duration were sought and, again, that existing containment facilities at Ruakura, or new facilities that would comply with relevant Standards, were to be used. Dr Allen noted that, by comparison to the earlier application GND02028 (see above [69]), the scope of the Import and Outdoor Development applications were far broader in a variety of ways. She concluded, however,

> I consider that as the applicant has clearly identified the broad nature of the proposed applications, that the research sites are unspecified and the request for approvals for an unlimited duration, the public did have sufficient information to make submissions about the applications (including voicing concerns about the broad nature of this application, the unspecified location of the containment facilities and the request for unlimited approval durations).

- The identification of the organism

[103] With reference to the chart produced at [53], Dr Allen first noted that the Import Application was, in effect, limited to species of the listed livestock genera which are already present in New Zealand – producing the chart depicted at above [55].

[104] Dr Allen also noted that the Applications are expressed in terms of genera and that species listed by the Convention on International Trade in Endangered Species (CITES) will not be used as host organisms, but that generic material might be sourced from those species.

[105] Dr Allen stated that HSNO was "organism-based", that approvals under HSNO are given for organisms and that the identification of a host organism is achieved by naming the genus or species to which that organism belongs. On that basis, she considered that the identification of host organisms at genus level was sufficient to determine the biological nature of that host organism and to identify that host organism as required under the Act and constituted sufficient identification.

[106] Dr Allen concluded:

> I consider that the genus level identification of the host organisms applied for to be imported or developed does in part fit the criteria of section 40(2)(a)(i) of the Act as the biological nature and the nature and degree or

> type of hazard intrinsic to host organisms within a genus have been identified by classification into a particular genus. However, this is subject to consideration of the genetic modification of that host organism.

[107] At paragraph 56, she noted that the project team may or may not recommend approval at genus level for all of the host organisms applied for, and could recommend, and ERMA could impose, a range of restrictions. She concluded:

> Therefore I consider that this information on the host organism in large part fulfilled the following section 40 of the Act requirement:
>
> - Section 40(2)(a)(i) of the Act: *"The identification of the organism"* for the GMD08012 and GMD07074 applications.
>
> The full identification is based on this in combination with information on the genetic modification which I discuss in a later section.

- The procedures and material to be used

[108] Dr Allen noted that the Import and Development Applications defined the genetically modified organisms applied for broadly by traits that relate to the four purposes of those Applications (see above [52] and [101]).

[109] She went on to refer to a variety of sections of the Applications which describe genetic modification technology and how the new genetically modified organisms to be developed might be produced (plus six types of modifications to be excluded). She also noted that AgResearch had listed examples (although not a definitive list) of the types of vectors to be used, the source of genetic material, the biological material that will not be used and examples of regulatory elements.

[110] Dr Allen noted that as HSNO does not specify the extent to which the genetic modifications proposed must be described the project team had to determine whether the Applications contained sufficient information to enable it to form a risk assessment on the proposed activities. She states that the degree of information required to conduct a risk assessment analysis increases when "higher risk" organisms are to be developed or used.

[111] At one point, Dr Allen notes that information on the proposed genetic modification should contain details on the procedures to be used to make the

genetically modified organism. She then comments that the applicant has provided an indicative list, indicating that normally required details on the procedures to be used had not been provided here.

[112] Again, Dr Allen notes that the project team could recommend a narrowing of any approval granted relative to the Applications.

- The containment system, nature and purpose of field tests and information relating to necessary controls

[113] In general terms AgResearch proposes a containment system that is, as its existing containment systems are, registered in accordance with s 39 of the Biosecurities Act and conforms to MAF and ERMA operational standards, and which generally follows the procedures used in the AgResearch containment facilities located at Ruakura. In addition, operational procedures are described. Referring to MAF/ERMA Standards, Dr Allen noted that those standards specify the measures that need to be undertaken to contain the organisms. There are different Standards for containment of micro-organisms and cell cultures, plants, invertebrates, laboratory animals, zoo animals and for the field testing of animals. All those Standards were and are available from the ERMA and MAF Biosecurity New Zealand websites.

[114] On that basis, Dr Allen concluded that AgResearch had supplied sufficient information on the containment procedures for genetically modified organisms to be imported and developed.

- Possible adverse effects on the environment

[115] Dr Allen noted that the Applications included tables which outlined the nature of potential adverse effects, the source of those potential adverse effects and the pathways by which those potential effects could occur. That analysis had been prepared using a defined methodology for identifying and assessing risks.

- Dr Allen's overall conclusion

[116] Dr Allen concluded as follows:

> As discussed throughout this affidavit, I have outlined why I consider that the supplied information complies with the information requirements of section 40(2) of the Act and how this information may be used during the risk assessment to be performed by the project team.
>
> These applications from AgResearch are broader than any similar application previously considered by the Authority and the information provided in these applications is indicative rather than definitive. In this regard I note that clause 29 of the Hazardous Substances and New Organisms (Methodology) Order 1998 states that where:
>
> > *"the Authority encounters scientific or technical uncertainty relating to the potential adverse effects of a substance or organism, or where there is disputed scientific or technical information, the authority – (a) must determine the materiality and significance to the application of the uncertainty or dispute taking into account the extent of agreement on the scope and meaning of the scientific evidence […]".*
>
> Clause 30 states that:
>
> > *"Where any scientific or technical uncertainty or dispute is not resolved to the Authority's satisfaction during its consideration of the application, the Authority must take into account the need for caution in managing the adverse effects of the substance or (to the extent provided for under the Act) the organism concerned."*
>
> The Authority can request further information from the applicant, the project team, submitters or from experts.
>
> During the consideration of these applications, the Authority can approved [sic] or decline the applications. If it approves the application(s), it can impose more stringent controls, narrow down the organism description or restrict the purposes for which the approval(s) can be used. Because of this, I consider that these applications contained sufficient information to begin this process.

AgResearch

[117] For AgResearch, affidavits were provided by Professor Paul Atkinson, Mr Timothy Hale and Mr Shaun Slattery.

[118] Professor Atkinson is a professor of chemical genetics at Victoria University. Prior to that he worked for AgResearch, and prepared AgResearch's Application GMD02028 for work with genetically modified cattle. He described, in general

terms, AgResearch's programme of transgenic research. He noted that if researchers were required to come to ERMA for approval at each iteration it would be impossible to undertake research of the nature he described.

[119] He also commented on the containment regimes and controls and their efficacies. As I read his affidavit, he generally expressed the view that techniques of genetic modification, and the results of genetic modification, are sufficiently predictable to enable approval to be given to the Applications, notwithstanding the broad range of species involved, both in terms of the livestock to be modified and the laboratory animals and other organisms to be used to facilitate the modification of those livestock species.

[120] Mr Hale is the manager of AgResearch's animal containment facility at Ruakura. He provided general background information as to the Standards followed, and the procedures involved, in establishing a new facility. He accepted Dr Hutchings' characterisation of the Applications as seeking a national protocol. He did not consider that inappropriate.

[121] Mr Slattery is a consultant providing advice to AgResearch on the Applications. Prior to that he had been employed by ERMA as Applications Manager. He described the process followed up until the current time and the process that would be followed from now until a final decision by ERMA. I do not consider that his evidence differs greatly from that of Mr Atapattu's.

[122] In terms of that evidence, I think the crucial affidavits were those provided by Dr Allen and Professor Atkinson.

Discussion

[123] The issues in this proceeding are, in my view, best understood in terms of the contrasting positions taken by GE Free and by ERMA itself.

[124] In response to the substance of GE Free's Applications, ERMA's reply, which has considerable appeal in a judicial review context, essentially categorised

GE Free's challenge to ERMA's decisions as being premature. That is, ERMA is the expert, science-based body charged with administering HSNO. The Applications had been made to it, and are acknowledged to be very general in their scope and, indeed, more general than ERMA has previously considered or granted. ERMA has drawn the risk of relevant aspects of the Applications to AgResearch's attention.

[125] ERMA's evidence is clear. It is well aware of the very general nature of the Applications, and the challenges that poses for the risk analysis task that ERMA is charged with under HSNO. In ERMA's view, therefore, what GE Free has done is to conflate the question of whether a valid application has been received with the question of whether an application should be approved.

[126] From ERMA's and AgResearch's perspectives, the correct approach is for this Court to decline to intervene at this stage, and allow ERMA to consider the Applications, in the terms Dr Allen has indicated it will. If, at that point, GE Free considers that ERMA has failed to properly carry out the risk assessment of effects and benefits fundamentally called for by s 45, whether by reason of the generic nature of the Applications, or by reason of some other failure on ERMA's part, then that is a matter which may properly be brought before this Court, either by way of judicial review or – as expressly provided by HSNO – by way of appeal on a point of law. Dr Allen's detailed evidence is essentially the answer to the plaintiff's claim. That is, the Applications do identify each of the matters called for, and allow ERMA to undertake the necessary risk assessments.

[127] There is, as I have indicated, considerable strength to that argument. In particular, and as recognised in the *MAdGE* decision, the decisions called for under HSNO are at their heart scientific and expert. They are not decisions with which this Court will readily interfere. Indeed, in *MAdGE*, Justice Potter put it in these terms (at [204]):

> Given that nothing in the Act expressly prohibits or prevents an application for more than one organism, i.e. a generic application, nor prevents [ERMA] from granting approval for more than one organism, i.e. generic approval; and given that whether or not there has been compliance with the Act's requirements will invariably depend on expert assessment as to whether there has been "identification" in terms of s 2 and the provision of information sufficient to meet the description and details

> required by s.40(2)(a) in relation to a development, there is no basis upon which the Court could or should intervene to substitute its assessment of the application for that made by [ERMA] as to whether the application fulfilled the statutory requirements for it to be *considered* by [ERMA]. That [ERMA] preferred its assessment of the information to the view taken by other experts including those for MAdGE, does not constitute a jurisdictional error which is reviewable by the Court.

[128] That approach, on its face, very much supports the position taken by ERMA and AgResearch.

[129] Against that, in my judgment, must first be set the scope of the Applications here. Application GMD02028, as considered in the *MAdGE* decision, was to develop in containment genetically modified *Bos taurus* (cattle) cells and cattle that can express functional therapeutic foreign proteins in their milk and transgenic cattle to study gene function and genetic performance. The application was to make cattle transgenic one gene at a time from a specified range of mammalian species utilising a list of regulatory elements for constructs to achieve successful transgenesis.

[130] The Applications themselves helpfully note the extent to which they go beyond that application:

a) The host organism in GMD02028 was a single species (*Bos taurus*). In these Applications the livestock species for which approval is sought are any species within nine livestock genera, with a range of additional genera required for additional work involving cell lines in small animals.

b) The source of the donor DNA inserted in GMD02028 is limited to humans, mice, cattle, sheep, deer or goats. In these Applications, donor DNA may come from animals, micro-organisms, viruses, plants or synthetic sequences and nucleic acids comprising sequences derived from animals, micro-organisms, viruses, plants or synthetic sequences and consist of coding, non-coding or regulatory nucleic acids with proven functions.

c) The organism description in GMD02028 permitted the use of only one gene of donor DNA at a time. There is no equivalent limitation in these Applications.

d) Approval is sought in these Applications for production of biopharmaceuticals and other products with commercial applications for release.

e) As to controls, amongst other differences, approval is sought without time limit and without breeding restrictions.

[131] More fundamentally, perhaps, I also note that the Applications, and in particular the Import Application, provide for the importation into New Zealand of new genetically modified forms of the various genera of the named species. There is no restriction on the type of genetic modification which might be involved in those imported organisms. There was no equivalent such broad starting point in GMD02028.

[132] In addition, the Applications are sought in relation to genetic modifications using "any technique available" – both existing at the present time and as developed in the future.

[133] Although the Applications list likely methods of genetic modification and examples of the types of vectors and sources of genetic and biological material to be used, these are not exhaustive and therefore do not delineate the scope of the Applications. Likewise, the purposes of the research are expressed inclusively.

[134] Reading Dr Allen's affidavit, and although the material is densely scientific, I was left with the conclusion that the Applications describe a broad range of experimental procedures, biological material and other matters which can best be described as being such as would facilitate the achievement of the four (but only inclusive) purposes referred to by AgResearch.

[135] By reference to the tables of adverse effects included in the Applications, I note that, again accepting the densely scientific nature of the background material, the Applications appear to identify all possible risks that could be associated with the import, development and field testing of genetically modified organisms. On this application, this Court is not concerned with the accuracy of this assessment – an inherently scientific enquiry – but with whether the assessment able to be undertaken is that which is envisaged by the scheme of HSNO. By reference to the wide range of genetically modified organisms involved in the Applications, it is difficult to see in the material provided how there had been any assessment of risk specifically associated with those organisms, either as originally genetically modified at the time of their importation, or as subsequently genetically modified in the course of the development work to which the Applications relate.

[136] In my judgment, Mr Hale's acceptance of Dr Hutchings' characterisation of the application as seeking a national protocol effectively confirms that analysis. Similarly, Professor Atkinson's affidavit confirmed that the risk assessment ERMA was being asked to make was based on the reasonably general proposition as to the risks associated with techniques of genetic modification rather than any more focused assessment.

[137] As the *MAdGE* decision has indicated, generic applications are able to be made under HSNO. Professor Atkinson's concern at the need for approval for each "iteration" is, therefore, in my view misplaced.

[138] In terms of risk assessment, and in considering GE Free's fundamental proposition, it is also necessary to place the details of the very detailed legislative scheme within the broader context of the scheme and purpose of HSNO itself. In this area of genetically modified organisms, the purpose of the information to be provided to ERMA is to enable ERMA to carry out a focused risk assessment. The scope of the Applications is such that:

a) There is, in my judgment, effectively little relevant limit on either the scope of genetically modified organisms which may be imported into New Zealand, or the subsequent genetic modification to which those

organisms might be subjected in the course of AgResearch's programmes (except insofar as the host organisms are limited to species currently in New Zealand or for which a new organism approval is given before the work commences).

b) Moreover, and in terms of containment and control, the Applications provide no specificity, as to location absolutely, and – beyond compliance with existing regulatory requirements – as to functionality of containment processes.

[139] In other words, in my judgment and as a matter of logic, it is difficult to see how ERMA can carry out any risk assessment relating to relevant genetically modified organisms or containment facilities, as it simply does not have information as to the nature of any specific genetically modified organisms for import, genetic modifications to those organisms in development and, as relevant to development and field testing, the location or nature of any yet to be constructed containment facility.

[140] I accept that ERMA can carry out a form of risk analysis with respect to the Applications. However, in my judgment that risk analysis effectively could only be carried out at a generic level, by reference to theoretically possible ranges of genetically modified organisms for import, subsequent modifications to those organisms in development and generally prevailing standards and requirements for containment facilities. Yet, if that type of generic analysis was sufficient, it is difficult to understand why Parliament would have gone to the length it did in HSNO apparently to require that determination of the risks and benefits associated with importing, development and field testing of specific genetically modified organisms and specific containment facilities should be undertaken. Rather, if that was the approach that was called for Parliament would simply have promulgated general regulatory controls, and allowed genetic modification, importation and research programmes to be conducted within the ambit of those controls, without specific risk assessment of specific proposals being required.

[141] In essence, the scheme of HSNO is not such as to provide for the establishment of a "national protocol" which, as acknowledged by Mr Hale from AgResearch, the Applications effectively seek approval for.

[142] In my judgment, and at key points, ERMA effectively acknowledges in its evidence aspects of the foregoing analysis.

[143] ERMA argued, at various points, that the generality of the Applications was not a bar to effective public submission. It also stated that it could approve the Applications subject to greater controls or reductions in their scope – for example giving approval in respect of specific locations, for a defined period of time, only in relation to certain species or organisms (for example, excluding those considered to have a significantly higher risk of escape), or only for particular purposes (see [116]).

[144] In a very recent decision *Wyeth v Ancare* [2009] NZCA 211 the Court of Appeal reversed the High Court's decision that the public scrutiny provided for in HSNO required the public release of confidential information as to the exact make-up of the hazardous substance in question. The Court noted that, while the identity of the substance had not been publicly disclosed, the publicly available information did identify important information about the substance such as its hazardous properties, the potentially significant risks to the environment, to human health and safety, to society and community and to economic interests, the types of control that should be imposed, and the overall evaluation of risks, costs and benefits. The Court also noted that ERMA was not dependent on public input in relation to the applicant's scientific claims, which were subjected to scrutiny by independent consultants who had access to all of the information. The Court noted that, on the facts of that case, the "critical information" for those wishing to make submissions was the information about the risks posed by the hazardous substance and the controls proposed. Therefore, the Court's conclusion that the confidential information should not be disclosed does not contradict the importance of public scrutiny of, and input into, for example, the assessment of risks and benefits and proposed controls.

[145] In my judgment, there is considerable strength to GE Free's point that the information necessary for effective public input here has not been made available (via the Applications or otherwise) given, if nothing else, the breadth and generic nature of the Applications.

[146] In the resource management context, the need for an application to contain sufficient particularity to enable meaningful submissions to be made is usefully summarised by the Planning Tribunal (now Environment Court) in *AFFCO NZ Ltd v Far North District Council (No 2)* [1994] NZRMA 224 at 234-5:

> … The description is intended to include whatever information is required for a consent authority to understand its nature and the effects that it would have on the environment. The description is expected to be full enough that a would-be submitter could give reasons for a submission about it and state the general nature of conditions sought. The application needs to have such particulars that the consent authority would need to be able to have regard to the effects of allowing the activity, and to decide what conditions to impose to avoid, remedy or mitigate adverse effects without abdicating from its duty by postponing consideration of details or delegating them to officials. …
>
> … Advisers to consent authorities and would-be submitters should not themselves have to engage in detailed investigations to enable them to assess the effects. It is an applicant's responsibility to provide all the details and information about the proposal that are necessary to enable that to be done. The proposal and the supporting plans and other material deposited for public scrutiny at the consent authority's office should contain sufficient detail for those assessments to be made.

[147] Both ERMA and AgResearch urged the Court to have considerable caution in adopting that approach in the context of HSNO, and ERMA's role under HSNO. As I understood the submissions, that caution related particularly to the very scientific nature of the decisions being made under HSNO, ERMA's position as an expert decision-maker and the ability under HSNO to assess risks on an ongoing basis. While I accept the general thrust of those submissions, nevertheless – and in line with HSNO's emphasis on public input – I conclude that that approach can provide guidance in this context.

[148] To enable effective public participation, sufficient particularity is required at the application stage. Where the generality of an application precludes this, therefore, it is not an answer that ERMA might subsequently "impose more stringent

controls, narrow down the organism description or restrict the purposes for which the approval is given ".

[149] On balance, therefore, and whilst I recognise the strength of ERMA's response to GE Free's Applications, I have concluded that in this instance the Applications are simply too generic to enable the risk assessment called for by HSNO to be meaningfully undertaken. In reaching that conclusion I have carefully considered whether I am trespassing on to a question which should properly be left to ERMA's scientific expertise. I have concluded that I am not. My conclusion is not reached on the basis of an assessment of those matters which Parliament has entrusted to ERMA, but on an evaluation of the scheme and requirements of HSNO as a matter of law.

Outcome

[150] GE Free's application for review is granted. I find that ERMA erred in law in receiving the Applications for determination under HSNO. In terms of my discretion as to remedy, I think the error is such that ERMA cannot continue to treat the Applications as if they were valid. I therefore order that ERMA's decision to accept the Applications as applications under s 40 of HSNO is set aside and ERMA is to take no further steps towards hearing and assessing the Applications.

[151] No submissions were made on the question of costs. GE Free has succeeded, and in the normal course costs would follow that event, in my view most probably on a 2B basis. If, notwithstanding those comments, the parties are unable to resolve the question of costs, they may file submissions no later than one month from the date of this judgment. No parties' submissions on costs are to exceed five pages in length, excluding any calculation schedules.

"Clifford J"