IN THE HIGH COURT OF NEW ZEALAND
AUCKLAND REGISTRY

CIV.2003-404-673

IN THE MATTER OF	the Judicature Amendment Act 1072
AND IN THE MATTER OF	the Hazardous Substances and New Organisms Act 1996
BETWEEN	MOTHERS AGAINST GENETIC ENGINEERING INCORPORATED
	Applicant
AND	THE MINISTER FOR THE ENVIRONMENT
	First Respondent
AND	THE ENVIRONMENTAL RISK MANAGEMENT AUTHORITY
	Second Respondent
AND	AGRESEARCH LIMITED
	Third Respondent

Hearing: 10 June 2003

Appearances: Peter Andrew and Jamie Ferguson for applicant
Bronwyn Arthur and Dhilum Nightingale for first respondent
Mary Scholtens Q.C. and Helen Sharpe for second respondent
Justin Smith, Kerry Marshall and Sophie East for third respondent

Judgment: 7 July 2003

JUDGMENT OF POTTER J

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Introduction

[1] Mothers Against Genetic Engineering Incorporated ("MAdGE") seeks under the Judicature Amendment Act 1972 judicial review of the actions of the Minister of the Environment ("the Minister") and of a decision of the Environmental Risk Management Authority ("the Authority" and "ERMA") given on 30 September 2002 ("the decision") to approve application GMD02028 by AgResearch Limited ("AgResearch") to develop in containment a genetically modified organism ("GMO"). Specifically the decision granted approval subject to conditions, for development by AgResearch of transgenic ("Tg") cattle that can express functional therapeutic foreign proteins in their milk and Tg cattle to study gene function and genetic performance.

[2] It needs to be clarified at the outset that the application for judicial review is concerned with the validity of the processes followed by the Minister and the Authority and with the interpretation of certain definitions in the Hazardous Substances & New Organisms Act 1996 ("the HSNO Act"). It is not concerned with the merits of the decision, nor the merits, or the risks associated with genetic modification (also called genetic engineering). Those perspectives must be developed elsewhere. The Report of the Royal Commission on Genetic Modification published in 1991 followed a full consultation process which enabled such perspectives to be presented and considered. The public hearing by the Authority in relation to application GMD02028 provided an opportunity for such perspectives to be presented in relation to the specific application of AgResearch. Accordingly, scientific evidence placed before the Court by MAdGE and in reply by some of the respondents, much of it containing conflicting opinion, is largely irrelevant to the issues before the Court. In particular, evidence as to risks which, in the opinions of the various deponents were, or were not, or not sufficiently considered by the Authority in relation to GMD02028 are matters for the Authority and have no place in the Court's deliberations on the application for judicial review.

Parties

[3] The applicant MAdGE is an incorporated society whose objects include promoting the non-use of GMOs and promoting education of families and communities on issues surrounding genetically engineered food to enable informed choices to be made.

[4] The first respondent is the Minister who administers the HSNO Act and regulations made under the Act including the Hazardous Substances and New Organisms (Methodology) Order 1998.

[5] The second respondent is the Authority which is established under s.14 of the HSNO Act as a body corporate with perpetual succession. The Authority has powers under the Act including the power to grant approval for the development, field testing and release of GMOs. The Authority is supported by the Crown entity ERMA New Zealand. In this judgment the terms "the Authority" and "ERMA" refer to both the Authority and ERMA New Zealand, as the context requires.

[6] The third respondent AgResearch is a duly incorporated company and a Crown Research Institute under the Crown Research Institutions Act 1992. AgResearch carries out scientific research including research involving GMOs and genetically modified animals.

Ambit of Judicial Review

[7] The High Court exercises an ancient supervisory jurisdiction over the exercise of discretionary powers by public bodies. In *Wellington City Council v Woolworths NZ Ltd (No 2)* [1996] 2 NZLR 537 the Court of Appeal considered a challenge by judicial review to the decision of a Local Authority, the Wellington City Council, setting rates under the Rating Powers Act 1988. Richardson P delivering the judgment of the Court of Appeal stated at p.545 –

> The legal principles are well settled and were discussed in *Mackenzie District Council v Electricity Corporation of New Zealand* [1992] 3 NZLR 41 at pp.43-44 and p.47. In summary, judicial review of the exercise of local

> authority power, in essence, is a question of statutory interpretation. The local authority must act within the powers conferred on it by Parliament and its rate fixing decisions are amenable to review on the familiar *Wednesbury* grounds. Rating authorities must observe the purposes and criteria specified in the legislation. So they must call their attention to matters they are bound by the statute to consider and they must exclude considerations which on the same test are extraneous. They act outside the scope of the power if their decision is made for the purpose not contemplated by the legislation. And discretion is not absolute or unfettered. It is to be exercised to promote the policy and objectives of the statute. Even though the decision maker has seemingly considered all relevant factors and closed its mind to the irrelevant, if the outcome of the exercise of discretion is irrational or such that no reasonable body of persons could have arrived at the decision, the only proper inference is that the power itself has been misused.

[8] The familiar *Wednesbury* grounds referred to by the President, were summarised in *Associated Provincial Picture Houses Ltd v Wednesbury Corporation* [1948] 1 KB 223 by Lord Greene MR at p.233 as follows –

> ... I will summarise once again the principle applicable. The court is entitled to investigate the action of the local authority with a view to seeing whether they have taken into account matters which they ought not to take into account, or, conversely, have refused to take into account or neglected to take into account matters which they ought to take into account. Once that question is answered in favour of the local authority, it may be still possible to say that, although the local authority have kept within the four corners of the matters which they ought to consider, they have nevertheless come to a conclusion so unreasonable that no reasonable authority could ever have come to it. In such a case, again, I think the court can interfere. The power of the court to interfere in each case is not as an appellate authority to override a decision of the local authority, but as a judicial authority which is concerned, and concerned only, to see whether the local authority have contravened the law by acting in excess of the powers which Parliament has confided in them.

[9] As to the test of "unreasonableness" Lord Greene had this to stay at p.230 of the judgment –

> It is true to say that, if a decision on a competent matter is so unreasonable that no reasonable authority could ever have come to it, then the courts can interfere. That, I think, is quite right; but to prove a case of that kind would require something overwhelming ...

[10] In *Wellington City Council v Woolworths* the Court of Appeal also cited from Lord Diplock in *Council of Civil Service Unions v Minister for the Civil Service* [1985] AC 374, 412 on the meaning of unreasonableness –

> It applies to a decision which is so outrageous in its defiance of logic or of accepted moral standards that no sensible person who had applied his mind to the question to be decided could have arrived at it.

[11] The Court further referred to *Webster v Auckland Harbour Board* [1987] 2 NZLR 129, 131 where Cooke P spoke of an unreasonable decision as "one outside the limits of reason". Richardson P then observed at p.545 that "Clearly, the test is a stringent one".

[12] A challenge to a decision of the Authority may also be mounted under the HSNO Act. Section 126 provides to a party to any application for an approval, or to any person who made submissions to the Authority on any application for an approval, the right to appeal against the decision of the Authority to the High Court. The appeal right is a limited right; it is restricted to questions of law. As was observed by McGechan J in *Bleakley v Environmental Risk Management Authority* [2001] 3 NZLR 213, 221 –

> This Court does not have de novo appellate jurisdiction under which it could reassess the authority's decision upon its merits, reaching perhaps a different view whether consent is warranted. We do not have power to engage in a second-stage general reconsideration. The Court's jurisdiction is limited by s.126(1) to questions of law arising in relation to the authority's decision.

[13] Thus, whether a decision of the Authority is challenged by judicial review or appeal, the merits are left firmly with the Authority, a body of experts established under s.14 of the Act whose members numbering 6-8 are appointed by the Minister to include pursuant to s.16 –

> ... a balanced mix of knowledge and experience in matters likely to come before the Authority.

[14] Any appeal must be filed within 28 days of the decision. In this case the judicial review proceedings were issued on 14 January 2003, well beyond the 28 day appeal period which expired towards the end of October 2002.

The HSNO Act ("the Act")

[15] Relevant provisions of the Act are set out in the schedule to this judgment. The Act deals with hazardous substances and new organisms. It specifically contemplates and provides for new organisms including GMOs.

[16] A new organism includes a GMO pursuant to the definition in s.2A. An organism ceases to be a new organism when an approval has been given in accordance with the Act for the release from containment of such an organism. There is currently a moratorium on release, current until 29 October 2003.

[17] The purpose of the Act as set out in s.4, 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.

Thus the focus of the Act is risk assessment and risk management.

[18] Section 5 states principles relevant to the purpose of the Act. Persons exercising functions, powers and duties under the Act are required to recognise and provide for the stated principles which include –

> the maintenance, enhancement of the capacity of people in communities to provide for their own economic, social, and cultural wellbeing ...

[19] Section 7 states a precautionary approach which again reflects the focus on risk management. The exercise of 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.

[20] Section 9 provides for a methodology to be established and for the Authority consistently to apply the methodology when making decisions. The methodology was established in the New Organisms (Methodology) Order 1998 ("the Methodology order") which was at issue in the *Bleakley* decision. That case concerned an appeal under s.126 of the Act against a decision of the Authority dated 21 July 2000 which approved an application to field test a GMO, Bos taurus, as

genetically modified by the insertion of sequence coding for human myelin basic protein in the milk of genetically modified cattle. The application followed a previously approved application for the development of genetically modified embryos under laboratory conditions. The Court considered the appeal under seven headings. The appellant was successful on one ground only, being the failure of the Authority to apply the methodology in the Methodology order. In particular there was a material error of law in the failure of the Authority to state the criteria of the methodology on which it relied in coming to its decision. Accordingly the decision of the Authority was set aside and the Authority was directed to reconsider and decide the application applying the Methodology order and stating the methodology criteria upon which it relied. In the course of its judgment the Court issued a word of warning to the Authority at para [296] –

> It must proceed case by case, with each taken separately on its merits. Decisions are not to be dictated by the desirability or undesirability of outcomes perceived exclusively from the viewpoint of advancement of science. Nor, despite New Zealanders' love of so-called "practical" considerations, do those prevail ahead of legal requirements.

[21] Section 25 prohibits any new organism from being imported, developed, field tested or released otherwise than in accordance with an approval issued under the Act.

[22] Section 39 authorises the Authority to approve the importation, development or field testing of any new organism into containment for purposes including the development of any genetically modified organism or the field testing of any new organism.

[23] Section 40 requires that application for approval to import, develop or field test a new organism in containment be made to the Authority. The application shall include information about the containment system for the organism. An application for the development of an organism shall include information concerning –

(i) *The identification of the organism*; and

(ii) The description of the project and the experimental procedures to be used; and

(iii) The details of the biological material to be used; and

(iv) The expression of foreign nuclear acid material; and

(v) *All the possible adverse effects of the organism on the environment.*

An application for field testing shall include information concerning –

(i) *The identification of the organism*; and

(ii) The purposes of the field testing; and

(iii) *The genetic modifications of the organism to be tested*; and

(iv) The nature and method of field trials and the experimental procedures to be used; and

(v) *All the possible adverse effects of the organism on the environment.*

(The italics indicate provisions to which I shall particularly return later in this judgment).

[24] Section 42 provides a rapid assessment procedure for low-risk genetic modifications.

Applications to develop low risk GMOs may be determined by institutional biological safety committees (IBSCs) of certain research institutions to whom the power of determination is delegated by the Authority pursuant to s.19(2)(a) of the HSNO Act. "Low risk" applications must meet the requirements of the HSNO (Low Risk Genetic Modification) Regulations 1998. A "low risk" development of a GMO must be in prescribed physical containment conditions that can be met only in indoor laboratories.

[25] Section 45 applies to development applications which do not meet the criteria for a low risk genetic modification pursuant to s.42.

[26] Under s.45(1) the Authority may in its discretion approve the application if –

(i) The application is for one of the purposes in s.39(1); and

(ii) After taking into account all the effects of the organism and any inseparable organism, the beneficial effects of having the organism in containment outweigh the adverse effects of the organism and any inseparable organism should the organism escape; and

(iii) The Authority is satisfied that the organism can be adequately contained.

The Authority is to decline the application in any other case.

[27] Sections 43 and 44 direct the Authority to matters it must consider when making a decision under s.45, including the ability of the organism to escape from containment.

[28] Section 44A of the Act was inserted by s.7(1) of the Hazardous Substances and New Organisms (Genetically Modified Organisms) Amendment Act 2002 ("the 2002 Amendment"). It followed from certain recommendations of the Royal Commission which reported in July 2001. Section 44A specifies additional matters to be considered by the Authority for developments of new organisms which do not take place in a "containment structure", and for field tests. A containment structure is defined as a containment facility that is a vehicle, room, building or other structure set aside and equipped for the development of genetically modified organisms. When the development is to take place outside a containment structure, and in respect of field tests, the Authority must take into account the following additional matters: any adverse effects on human health and safety and on the environment, in particular eco systems and their constituent parts; any alternative method of achieving the research objective than the development or field test proposed; and any effects resulting from the transfer of any genetic elements to other organisms in or around the site of the development or field test.

[29] Section 45A also inserted by the 2002 Amendment, deals with controls required for developments of new organisms outside a containment structure and to field tests of new organisms. The approval must include controls to ensure that the organism and any heritable material (i.e. material capable of regenerating or reproducing) from the organism is removed or destroyed, and may include controls to ensure that after that is done some or all of the genetic elements remaining from the organism are removed or destroyed. Subsection (3) provides that destruction may be achieved by leaving genetic elements to break down or to become inactive at the site of the development or field test.

[30] Under s.53(2) development applications not dealt with pursuant to the rapid assessment provisions *may* be publicly notified if likely to be of significant public interest. Field test applications *must* be publicly notified under s.53(1)(d).

[31] Under s.58 the Authority may commission a report or seek advice from any person on any matters raised in the application including a review of any information provided by the applicant.

[32] Section 59 provides time limits in relation to applications, and specifically provides in subsection (4) that the Authority shall not extend or reduce any time period or grant any application to waive a requirement as to a time period unless the applicant and submitters consent to the waiver or will not be unduly prejudiced.

[33] Under s.61(3) the Authority in relation to applications has the same powers as conferred on a commission of inquiry by the Commission of Inquiry Act 1908.

[34] Sections 62 and 63 provide for reassessment of a substance or organism where (inter alia) there is significant new information relating to the effects of the substance or the organism.

[35] Section 68 confers on the Minister the power to call in applications in certain circumstances.

The Minister may direct that she will decide the application and must give reasons for giving the direction. The Minister must notify her direction in the Gazette not later than 15 working days after receipt by the Authority of the application (s.69). The Minister is required to forward a copy of the Gazette notice to the Authority and the Authority then inquires into and reports on the application under ss.71 and 72 of the Act. In doing so, the Authority follows essentially the same procedures as if it were hearing an application. The Minister under s.70 may appoint additional persons with relevant knowledge or experience to sit with the Authority and to exercise the power of a member of the Authority. On completion of its inquiry the Authority is required to submit a written report to the Minister including recommendations and reasons. That report is made available to the applicant and to persons who made submissions. Within 20 working days after receiving the Authority's report the Minister shall give her decision in writing, including reasons.

Application GMD02028

[36] On 1 May 2002 AgResearch submitted application GMD02028 ("the application") to the Authority. It was made pursuant to s.40(1)(b) of the HSNO Act to develop a new organism in containment.

[37] The stated objectives of the application were –

a) To develop genetically modified Bos taurus (cattle) cells and cattle that can express functional therapeutic foreign proteins in their milk; and

b) To develop Tg cattle to study gene function and genetic performance.

[38] The application involved the use of transgenics and cloning. By cloning a single cell nucleus containing an animal's entire genome (all the animal's genes and other DNA) is used to re-programme embryonic cells to produce an animal genetically identical to the animal which donated the genetic material.

[39] Transgenesis is the crossing of genes across different species. A Tg organism is one in which foreign genetic material has been incorporated into the recipient's genome. The cattle produced as the result of genetic modification will be Tg clones.

[40] AgResearch acknowledged that the application was generic in the respect that the specific molecular detail of the constructs of the GMO were not provided. The application was to make cattle transgenic one gene at a time from a *range* of mammalian species utilising a list of regulatory elements for constructs to achieve successful transgenesis. The range of mammalian species contributing genes to the transgenic cattle are cattle, sheep, goat, deer, or mice, copy human. The generic nature of the application received considerable emphasis from MAdGE and is the subject of the fifth cause of action.

[41] The GMOs produced and transferred to conventional cattle would result in transgenic calves. The application sought approval for testing to evaluate whether the transgenesis and expression of functional therapeutic foreign proteins in their milk, had been successful.

[42] The application sought approval for a period of ten years. It proposed that the development of genetically modified cattle would span 3-4 years during which period the genetically modified cattle would be produced and the analysis of inheritance phenotype and protein expression in milk would be carried out. (The approval given by the Authority was for 7½ years).

[43] There were six parts to the proposed research covered by the application –

a) The isolation and culture of cell lines;

b) The isolation of DNA, libraries and gene constructs;

c) The transfection and selection of stable cell clones;

d) Nuclear transfer;

e) The generation of live offspring from cultured embryos;

f) The checking of gene stability through reproduction.

[44] Steps (a)-(d) comprise an initial laboratory phase where genetically modified embryos are created. Steps (e) and (f) comprise an outdoor phase of creating, breeding and testing the fully grown genetically modified cattle. It was common ground that steps (a)-(d) comprise a proposal for low risk genetic modification in containment. MAdGE contends that steps (e) and (f) could not be considered as part of an application for development of a GMO; rather they are an application to field test a new organism in containment. This is the subject of the sixth cause of action.

[45] Application GMD02028 was preceded by an application by AgResearch which related only to the steps which became (e) and (f) in GMD02028. This was application GMD01194 received by the Authority on 21 December 2001. As advised to the Minister, it was for approval to transfer transgenic embryos to recipient cattle and to evaluate the expression of the transgene, the ultimate purpose of the development being the production of pharmaceutical products to meet unmet human health needs. The application was expressed to be on a "project basis" rather than on a "single organism" basis. AgResearch claimed –

> The containment facility has the characteristics of an outdoor laboratory in order to provide animals with healthy living conditions while the transgenes of interest are studied.

[46] On 11 April 2002 AgResearch advised the Authority that it was withdrawing application GMD01194. Apparently AgResearch decided after discussion with the Authority that rather than approaching the application for approval on a two-stage basis, i.e. the equivalent of stages (e) and (f) in GMD02028, followed by applications for stages (a) to (d) for assessment on a low risk basis pursuant to s.42 of the HSNO Act, the approval should be sought pursuant to a single application which dealt with all stages of the project, presented by AgResearch as a development.

[47] When the Minister was advised of GMD02028 the letter from the Authority stated –

> This application is a substitute for application GMD01194 which AgResearch withdrew on 11 April. The previous application covered only those portions of a project which were outside the scope of AgResearch's IBSC to consider under delegated authority whereas the new application encompasses the full range of the development work from generation of the gene constructs, through implantation of modified embryos and recipient cows to produce transgenic calves, to the development of lines of GM cattle to check gene stability and to characterise gene expression.

[48] MAdGE drew attention to a letter to the Minister of 17 December 2001 which preceded receipt of GMD01194. The letter stated –

> This application is cast as an application to develop GMOs despite the fact that it is similar in almost all respects to previous applications which were considered as field trials. The "reclassification" is however, quite consistent with current ERMA New Zealand policy.

The letter continued –

> In essence the application is more clearly a development of a GMO rather than the evaluation of a GMO that has already been developed even though animals are to be contained in a field and not a laboratory. The location of the experiment is incidental to the actual objectives of the research because the definition of development in the Act relates to purpose only.
>
> This classification of the work is likely to excite comment, both because of the past history of similar work and the fact that the GMO Bill is currently before Parliament. Classifying the work as a development means that (potentially) it does not need to be publicly notified and it avoids the mandatory controls in the GMO Bill. However, in practice it is likely to make very little difference to the treatment of the application.

(The GMO Bill became the 2002 amendment to the Act which inserted ss.44A and 45A directed to developments which do not take place in a containment structure, i.e. are conducted outdoors and to field tests).

[49] The Minister did not call in GMD11094 pursuant to s.68.

Processing Application GMD02028

[50] As required by the tight timeframe in the Act the Authority responded promptly to application GMD02028 received on 1 May 2002.

[51] On 2 May 2002 the Authority notified the Minister that the application had been received, outlined the application in general terms and advised the Minister when the period would end in which she could exercise her statutory discretion to call in the application for her own decision. By s.69(1) the Minister has 15 working days from the time the application was received by the Authority to exercise her discretion to call in the application under s.68 of the Act. In this case any decision by the Minister to call in had to be notified in the Gazette on or before 22 May 2002.

[52] On 13 May 2002 the application was verified by the Authority as containing sufficient information for processing.

[53] On 15 May 2002 the Authority publicly notified the application under s.53(2) of the Act which gives the Authority a discretion to publicly notify any application to import or develop any GMO in containment which has not been approved under the rapid assessment procedure for low risk genetic modification. Section 53(2) provides for the Authority to exercise its discretion to notify an application, if it considers there is likely to be significant public interest.

[54] On 16 May 2002 pursuant to s.19(2)(b) of the Act, a committee was appointed to hear and determine the application. It comprised four members of the Authority plus Dr Manuka Henare appointed for his expertise and knowledge in Maori culture and traditions.

[55] The application was reviewed by ERMA staff and external consultants who produced an evaluation and review report ("E & R report"). On 29 July 2002 a copy of the report was provided to the Authority, AgResearch and each of those persons who had made submissions and indicated that they wished to be heard on their submission (391 submitters so notified, although only 25 of these ultimately appeared at the hearing).

[56] On 30 July 2002 other submitters and interested persons were advised by letter or email that the E & R report was available on the Authority's website and would be provided on request.

[57] On 13-15 August 2002 the hearing of the application was held in Hamilton. MAdGE made a written submission on the application and was represented at the hearing.

[58] On 28 August 2002 the Authority decided to approve the application. On 30 September 2002 the decision was issued containing the approval of the Authority.

[59] The above timeframe complied with the rigorous requirements of s.59 of the Act for processing, notifying, receiving submissions and commencing any public hearing, subject to extensions of time for holding the hearing and issuing the decision made pursuant to s.59(4) and (5).

The Authority's decision

[60] The Authority's decision and the reasons for it are set out in a lengthy written decision dated 30 September 2002, signed by Lindie Nelson, Deputy Chair of the Special Committee of the Authority appointed to consider the matter. I shall briefly summarise it here. Relevant parts of the decision are referred to in more detail in other sections of this judgment.

1. The Committee of the Authority determined that pursuant to s.45(1)(a)(i) of the Act it was satisfied that the AgResearch application was for one of the purposes specified in s.39(1), being s.39(1)(a), and that the scope and content of the application was acceptable for an application for that purpose –

> Notwithstanding the generic nature of the organism description in the application, the Committee is also satisfied that the application contains sufficient information on the organism to enable the application to be validly considered.

2. To ensure that the work covered by the decision was implemented as a development, controls on breeding were imposed. To reduce uncertainty associated with the assessment of effects of the organism, the scope of the approved organism was reduced from that set out in the application.

3. The Committee was satisfied pursuant to s.44A(2)(b) of the Act that having considered alternative methods for achieving the research objectives there were no practical alternatives with demonstrably fewer adverse effects.

4. The Committee was satisfied that the proposed containment regime together with the additional controls it imposed would adequately contain the organisms and that the controls would ensure that after the end of the development the organisms and any heritable material from the organisms were removed or destroyed (s.45(1)(a)(iii); s.45A(2)(a)).

5. The Committee recorded that in reaching its conclusion it had applied the balancing tests in s.45 of the Act and clause 27 of the Methodology order as required by clause 36(2)(b) of the Methodology order, and

6. Approval was given for development of genetically modified cattle that conform with the organism description in Annex 1 and are subject to the controls set out in Annex 2 to the decision.

Did the Minister unlawfully abdicate her statutory function or act unreasonably?

Pleading

[61] The first cause of action in MAdGE's statement of claim pleads that the Minister's failure to consider whether she should call in and decide the application under s.68 of the HSNO Act, was unlawful.

Particulars

a) The Minister's failure is a reviewable exercise of a statutory power of decision under the Judicature Amendment Act 1972.

b) The Minister's call in powers under s.68 are an integral part of the risk management scheme of the Act.

c) The Minister's failure to consider whether she should call in and decide the application was an unlawful abdication of statutory function.

d) The Minister did not consider at all –

i) Whether the application would have any significant economic effects, in particular the economic consequences of New Zealand losing its GE free image in agriculture; or

ii) Whether ERMA lacked sufficient knowledge or expertise in ethical or moral issues; or

iii) Whether consideration of the application should have been deferred pending determination by the Government of the issue of liability for adverse environmental or public health effects of new organisms.

[62] The second cause of action in the statement of claim pleads -

The failure of the Minister to consider whether to call in the application under s.68 was unreasonable.

Particulars

a) The application was the first generic transgenic application to be determined by ERMA under the Act.

b) The application was the first application involving animals to be determined by ERMA since the release of the Report of the Royal Commission on Genetic Modification.

c) The application was the first application to be determined under the Act as amended by the Hazardous Substances and New Organism (Genetically Modified Organisms) Amendment Act 2002.

d) The Minister was aware of the recommendation of the Royal Commission on Genetic Modification that a Bio Ethics Council be established and that such Council should have a particular role to play in relation to transgenic animal applications.

e) The Minister was aware that one of the greatest areas of public concern over genetic modification is over the mixing of human and animal genes.

f) The Minister was aware that liability for adverse environmental or public health effects of new organisms under the Act is a complex issue requiring urgent consideration by the Government.

[63] The relief sought in the statement of claim is -

a) An order that the failure of the Minister to consider exercising her call in powers under s.68 of the Act was unlawful.

b) A declaration that the Minister's failure to consider exercising her call in powers under s.68 of the Act invalidated the subsequent decision of ERMA to approve of AgResearch's application, and that such approval is therefore unlawful and of no effect.

c) An order that the Minister consider whether to call in and decide the application under s.68 of the Act.

d) Costs.

[64] In submissions before the Court, counsel limited the relief sought to a) recognising that the time for the Minister to exercise her call in powers has expired.

[65] The Minister's response is that –

a) She did not refuse or fail to exercise a discretionary power;

b) Before she can exercise her power to call in a criterion in s.68(1) of the HSNO Act has to be triggered and none was triggered by the AgResearch application;

c) As the application did not trigger a s.68 criterion it was not unreasonable for the Minister not to consider the exercise of her call in power.

d) She does not personally consider every application notified to her by the Authority but relies on her officials at the Ministry for the Environment ("the Ministry") to undertake an assessment and advise if she should consider the exercise of her call in powers.

Section 68

[66] The Minister's power to call in is conferred by s.68 of the Act which materially provides as follows –

> (1) Where the Minister considers that the decision on any application under this Act will have—
>
> (a) Significant economic effects; or
>
> (b) Significant environmental effects; or

(c) Significant international effects; or

(d) Significant health effects; or

(e) Significant effects in an area in which the Authority lacks sufficient knowledge or experience, -

the Minister may direct that the Minister will decide the application.

(2) The direction shall include the Minister's reasons for giving it.

[67] If the Minister decides to exercise her power of call in she must notify her decision in the Gazette not later than 15 working days after receipt by the Authority of the application. In this case any decision by the Minister to call in would need to have been notified in the Gazette by 22 May 2002. This time limit was advised to the Minister in a letter from the Authority to the Minister dated 2 May 2002. That letter advised receipt by the Authority of application GMD02028 and attached the Application Summary. The letter states that a copy has been forwarded to the Ministry for the Environment.

Evidence

[68] Steven Vaughan in his affidavit sworn 24 April 2003 states that he is employed by the Ministry and in 1992 set up the team responsible for development of the HSNO Act. He led this team throughout the development of the policy and passage of the Act and subsequent regulations. When application GMD02028 was received by the Ministry he held the position of Manager of the Hazardous Substances and New Organisms Group ("the HSNO Group"). As Manager of that group he had the primary responsibility for matters relating to the Act within the Ministry and it was he along with members of his team, who considered AgResearch's application for the purpose of deciding whether to advise the Minister as to the exercise of her call in powers.

[69] He states in his affidavit that he does not recall discussing with the Minister, the Ministry's process for reviewing ERMA applications, nor is that process set out in any internal documents. He describes a "process" which he states was established by him and members of the HSNO Group at the time that the Act was brought into force for new organisms. The process was established bearing in mind the short

time-frame available for call in and the need to consider as efficiently as possible and with limited resources, whether and if so in what form, the Minister should be advised about the possibility of calling in a particular ERMA application.

[70] His affidavit then describes under the heading "initial assessment" the procedure he follows upon receiving notification from ERMA of an application. He states that he notes the period for call in and reads through the notification letter and Application Summary. He looks at issues of particular significance and considers whether the application has any features, in particular any significant economic, environmental, international or health effects which would justify advising the Minister that she call in the application under s.68. He also considers whether ERMA would have the experience and capability to deal with the particular application. At that point, which he says is "usually that same day" as the notification documents are received, he hands them to the Policy Analyst in the HSNO Group who has lead responsibility for ERMA liaison. This person in the case of application GMD02028, was Jonathan Coakley.

[71] Mr Vaughan states that to date the initial assessment he has carried out in respect of any application notified by ERMA has not identified any significant effects which might justify call in. If it did he would immediately bring together relevant staff in order to prepare advice for the Minister, knowing the short time-frame for calling in the application.

[72] In the case of application GMD02028 Mr Vaughan states –

> I recall receiving around May 2002 a copy of a letter from Dr Bas Walker the Chief Executive of ERMA notifying receipt of an application by AgResearch (application GMD02028) to develop in containment transgenic cattle which would produce therapeutic proteins in their milk for medical research purposes. The letter enclosed AgResearch's Application Summary.

[73] He has not been able to locate this letter on the Ministry files but believes it was a copy of the letter sent to the Minister dated 2 May 2002. Nor can he locate a further letter dated 13 May 2002 from the Authority to the Ministry addressed to him personally, advising that AgResearch's application has been verified. That letter bears Jonathan Coakley's initials, a matter to which he refers in his affirmation. Mr

Vaughan says he recalls reading ERMA's notification letters and looking, as he did with all notification letters, for any particular features of the application that might justify call in. He states –

> I remember thinking at the time that AgResearch's application was not sufficiently significant in respect of the matters set out in s.68 to justify advising the Minister about a possible call in ... I also remember thinking at the time that as a significant proportion of applications being considered by ERMA involved genetic modification, ERMA had the capability and expertise to deal with an application to develop transgenic cattle.

[74] He handed the notification letters to Jonathan Coakley to carry out a "second assessment" of the application –

> ... probably within 24 hours of receiving each letter.

He did not make a written record of his assessment, nor did he discuss it with any staff member or with the Minister's office.

[75] He notes he was aware of the general nature of the application. AgResearch had obtained approval for a similar field test project in conjunction with PPL Therapeutics Limited and he recalled receiving notice from ERMA in January 2002 of a similar development application, GMD01194, which was withdrawn by AgResearch on 11 April 2002 and substituted with application GMD02028.

[76] Mr Vaughan did not consider the application further until the Minister's office sent him correspondence from John Carapiet dated 6 August 2002 and from MAdGE dated 3 October 2002, the first asking the Minister to exercise her call in powers, the second requesting a copy of the Minister's decision not to call in the application. He instructed staff in relation to the advice to be given to the Minister in response to those letters. Draft responses were checked and approved by him to be sent to the Minister's office.

[77] Jonathan Coakley in his affirmation of 21 May 2003, states that he is a policy adviser in the Working and Central Government group of the Ministry. At the time of the application he was a member of the HSNO Group. As policy analyst he has particular responsibility to advise the Minister on issues related to the sound environmental management of hazardous substances. In 2001 he was given

responsibility for liaison between the Ministry and ERMA. He reviewed application GMD02028 for monitoring purposes and also for the purpose of advising the Minister as to her call in powers under the HSNO Act. Mr Coakley describes a review process which he says was developed by the HSNO Group in conjunction with ERMA. ERMA advises the Ministry and the Minister's office of any application received and the call in period applicable. All such letters of advice went to the Manager of the HSNO Group but now go to the manager, Working with Central Government group. The manager undertakes an initial review then distributes the advice letters to a policy analyst for a more detailed review. The policy analyst considers whether a decision on the application would have significant effects in any of the areas set out in the HSNO Act for the Minister's call in powers. If the policy analyst considered that a decision on an application could trigger any of the statutory call in criteria and therefore the Minister may wish to consider her call in powers, the analyst would advise the manager who in turn would advise the Minister. He confirms that there is no written procedure for call in reviews but states that policy analysts involved with the HSNO Act "... are aware of this process". Applications from ERMA are received at the rate of approximately 5 to 10 per month. Since late 2001 when he was appointed to the ERMA liaison role he has reviewed approximately 10 applications relating to new organisms and 50 applications relating to hazardous substances.

[78] Mr Coakley described monthly liaison meetings between staff of ERMA and the Ministry at which a range of issues are discussed including up-coming and new applications to ERMA. He states that often therefore, by the time the Ministry receives the application notification from ERMA he is already aware of the application generally.

[79] He confirms the initial assessment role described by Steven Vaughan in his affidavit and that he would receive the notification documents from Mr Vaughan to co-ordinate a further assessment.

[80] He would review them as soon as possible, bearing in mind the 15 day timeframe for call in. He looked out for any features that he thought might justify the application being called in under the statutory call in criteria. Such features

include the nature of the application, whether ERMA has already decided similar applications, the possible risk to human health and the environment if the new organism or hazardous substance was not contained, likely public reaction and the capacity and capability of the Authority.

[81] He states that as his liaison role with ERMA specifically includes co-ordinating advice for the Minister on appointments of Authority members, he and other members of the HSNO Group were all well aware of who the Authority members were and their expertise. He states –

> The political, economic and social context are always in my mind, especially with respect to genetic modification applications as such applications are often controversial and may have impacts on New Zealand society and economy.

[82] Once he has reviewed ERMA's notification letter and the application summary he initials the letter. If he considers that his knowledge and expertise does not cover all of the areas that need to be considered by the Ministry in order to make an informed decision on call in or other Ministry involvement in relation to a particular application, he approaches the appropriate policy analysts in the team who have expert knowledge and experience in the particular area. He briefly discusses the application with the appropriate analyst or analysts and asks them to further review the application to assess in their view if the Ministry should provide a briefing to the Minister recommending call in or should provide comments or a submission on the application. This he states, in effect provides a third check. Those policy analysts would report directly to the manager if they had concerns. He would discuss any concerns he had with the manager. He states that as there has not yet been any applications for release of a GMO, the GMO applications to date have been considered in the context of development and field trials within a contained environment.

[83] Once the application has been through this assessment the ERMA information is placed on either the file dealing with hazardous substances or the file dealing with new organisms. There is no report to the Minister about an application where the assessment concludes that the application does not raise concerns about the significant effects as identified in s.68 of the HSNO Act.

[84] If Mr Coakley considered there were effects greater than normal (but not necessarily significant) he would raise and discuss them with his manager. To date no application has crossed the threshold where the Ministry have considered that call in may be appropriate.

[85] Mr Coakley states that he recalls receiving from Steven Vaughan in early May 2002 letters from ERMA providing notification of application GMD02028. It was not the first time he had heard of the application as it had been discussed in the monthly liaison meetings between ERMA and Ministry staff. It was also similar to application GMD01194 made by AgResearch in December 2001 and subsequently withdrawn. The earlier application had been discussed at a liaison meeting and had been assessed by Mr Vaughan and himself in early 2002. He recalled receiving the notification letter of 13 May 2002 which he initialled and ticked to indicate that he had considered it. He states that his consideration followed the process outlined above and took into account the earlier considerations and similar applications including GMD01194. He states –

> The application was to develop in containment a new organism. The summary of the application made it clear that it was for a "project" with one host being "cattle" but with a range of "donor" species, including human genes. It was also clear that the cows were to have calves, which would also mature to have milk. Although these animals would be in a containment facility, the facility included pasture, allowing the animals to be outside. None of this was new. I did not consider that there was anything in the application that would trigger significant economic, environmental, international or health effects.

[86] He states that he had no reason to believe that the Authority would not be able to deal with this application. He knew that some of the Authority's members had expertise in ethical issues and that it was possible to appoint other persons with particular knowledge or expertise to a committee appointed to hear and determine an application. He considered that the Authority was able to impose the controls necessary to ensure strict containment. He noted that the moratorium that was in place applied to release, not to development applications, which this was. Nor was it the Government's intention that the Bioethics council, which the Government was in the process of establishing, would have the role of advising on specific applications to ERMA. However, because he was aware that the application would have significant public interest he sought advice from one of his colleagues in the HSNO

Group who had more specific GMO expertise to ascertain whether that colleague considered that the Ministry should make a submission on the application. The colleague raised no concerns concerning the application.

[87] The Minister, Marion Hobbs, in her affirmation of 20 May 2003 states that she has held the environment portfolio since November 1999 (although she stood down from that position during March and April 2001). She notes that through the Ministry for the Environment she has responsibility for administration of the HSNO Act and that ss.68-73 provide her with the ability to call in applications for both hazardous substances and new organisms where she considers a decision on the application will have significant effects.

[88] She states that she is well aware of her power to call in a particular application if she considers certain matters warrant it. When she became Minister she was briefed by the Ministry and by ERMA on her various roles, including advice about the HSNO Act and her power to call in an application under that Act, with the Ministry providing advice and assistance. She meets regularly with Dr Bas Walker Chief Executive of ERMA to discuss the HSNO Act and her functions under it (including call in, and applications). She states –

> I consider that the purpose of the call in is to enable me as Minister to decide an application that has significant implications (significant economic, environmental, international or health effects or significant effects in other areas). This does not necessarily mean that the Authority does not have the expertise to consider the significant effects; indeed it is still responsible for undertaking the task of conducting the inquiry and providing me with advice. In some cases, however, it may be more appropriate for the Minister to make the final decision.
>
> I note however that the Authority is already a national expert body. As Minister, I have a function in appointing members to the Authority with a balanced mix of knowledge and experience in the matters likely to come before the Authority. The power to call in an application is not a power that I am likely to exercise very often.

[89] She notes that ERMA notifies the Minister by letter with a summary of the application attached of every application received which is likely to be notified. She is aware that ERMA also sends notification of applications to the Ministry and that the Ministry has its own processes to assess the applications. One of the purposes of that assessment is to provide her as Minister with advice on whether an application is

likely to trigger a significant effect so that she may wish to consider her call in powers.

[90] The Minister states that application GMD02028 was not the first application by AgResearch relating to transgenic cattle. She was aware of the *Bleakley* case and had been briefed on the High Court decision. She was aware that AgResearch intended to file a further application in relation to transgenic cattle. She states that she is very much aware of concern in the community about the transfer of genes from one species to another, particularly the transfer of human genes into other species. These community concerns were one of the reasons for the establishment by the Government of the Royal Commission on Genetic Modification in May 2000. She has carefully considered and discussed with officials the Royal Commission's 2001 report.

[91] In accordance with usual practice for applications that may be notified ERMA advised her of application GMD02028 by letter of 2 May 2002. She understood from the summary of the application that it was for a "project" rather than a single organism and that the donor species could include genes copied from humans. She also understood that the application was for a development, with most of it occurring within laboratories but that the cows and calves would be in a containment facility that included pasture. She did not have any concerns that the application was likely to give rise to significant effects. She recalled that it was not significantly different from the earlier transgenic cattle applications by AgResearch.

[92] Her office also received the verification letter dated 13 May 2002 but she did not see it at that time. She relied on her advisers at the Ministry to bring to her attention any potential significant effects relating to the application. They did not do so. She did not expect to hear from them if they did not consider that a decision on an application would trigger any significant effects. In the circumstances she did not have any reason to consider the exercise of her call in powers. Nothing she has considered since has caused her to question that approach.

[93] Because the 15 day call in period expires automatically, she does not consider that there is any need to advise ERMA that she is not calling in the

application. Once the call in period expires she has not further interest in the application under the HSNO Act.

[94] In relation to the Bioethics council, the Minister states that the purpose of that council is not to consider individual applications but to be a Ministerial advisory committee to provide advice to Government on bio-technology issues involving significant cultural, ethical and spiritual dimensions; to promote and participate in public dialogue, on cultural, ethical and spiritual aspects of bio-technology; and to provide information on the cultural, ethical and spiritual aspects of bio-technology. The Bioethics council was not established at the time that application GMD020208 was made, but she says that even if it had been, there would have been no purpose in calling in the application for referral to the Bioethics council because that is not the role of that council. Further, she is not aware of any powers under the HSNO Act that enable applications to be placed on hold, even if she had considered that desirable. The Minister concludes –

> To date I have not called in any application, nor have I been advised by Ministry officials of any application that is likely to trigger significant effects. This, to me, is not surprising. Most applications are not unusual and are readily dealt with by the Authority. Some applications are controversial, as this one relating to transgenic cattle development clearly is. Just because something is controversial does not, however, mean that the Authority should not make a decision on the application.

Submissions

[95] Submissions for MAdGE were presented in respect of both the first and second causes of action on the basis that the second cause of action is an alternative to the first cause of action. While the manner in which the first cause of action is framed might suggest that consideration by the Minister personally was required, this was not the thrust of MAdGE's submissions. Rather MAdGE submitted that whether the approach taken by the Minister's advisers in the Ministry is to be characterised as an abdication of statutory function (i.e. no decision was made because the approach was so cursory) or is a decision that no reasonable decisionmaker could have made (again because it was so cursory), it was unlawful. The focus of MAdGE's submissions was that in the process adopted by the Ministry

there was no adequate consideration of the application given the close scrutiny clearly intended by Parliament.

[96] MAdGE quoted from *Constitutional and Administrative Law in New Zealand* (second ed: Ed PA Joseph) at p.801 –

> A public authority must not disable itself from exercising its discretion in individual cases. When an authority is entrusted with discretionary powers, discretion must be brought to bear in every case. Each case must be considered on its merits and decided as the statute and public interest may require. An authority must not: ... refuse or fail to exercise its discretion. An authority abdicates its statutory function if it does [that] without Parliament's authorisation.

[97] MAdGE considered the Minister's call in powers and the manner in which they should be exercised in the context of the statutory scheme, and submitted that the HSNO Act imposes a strict and rigorous risk management regime. The Minister's call in powers are part of this regime and subject to the general purposes of the Act including the precautionary approach set out in s.7.

[98] MAdGE referred specifically to there being no written record of any assessment being made including any reasons on whether to call in application GMD02028. Counsel referred to the observation of the Court of Appeal in *Fiordland Venison Ltd v Minister of Agriculture & Fisheries* [1978] 2 NZLR 341, 346 –

> ... in the normal course those affected by administrative decisions are entitled to an explanation.

[99] The Minister was not specifically advised by the Ministry on application GMD02028, nor for that matter of any application likely to trigger significant effects. MAdGE's submissions commented that –

> This is rather surprising, given the importance and high degree of public interest in genetic modification and the fact that it is in a relatively nascent stage of its development.

[100] Much emphasis was placed by MAdGE in its submissions on "novel" aspects of the application: that it was for a development to be carried on outdoors; that the broad organism description "pushed at the boundaries" of what was acceptable for

the Authority, as acknowledged by Mr Currie of ERMA in his affidavit; that it was on a "project" rather than a single organism basis (not previously determined because GMD01194 had been withdrawn by AgResearch); that it would be decided under legislation that at the relevant time was about to be enacted, i.e. the 2002 Amendment which received assent on 27 May 2002 and inserted ss.44A and 45A providing for additional matters and controls for certain developments outside a containment structure and field tests. These aspects were acknowledged by the Authority as distinguishing features of GMD02028 yet, submitted MAdGE, no attempt was made by the Ministry to come to grips with them.

[101] MAdGE also made submissions on economic effects (s.68(1)(a)), and on ethical issues which MAdGE submitted although not specified in s.68 are incorporated within "environmental effects" (s.68(1)(b)) by the definition of "environment" in s.2 (which includes eco-systems and their constituents parts, including people and communities; all natural and physical resources; amenity values; the social, economical, aesthetic and cultural conditions which affect those matters or which are affected by those matters).

[102] MAdGE had concerns that any economic benefit flowing from the AgResearch project approved pursuant to application GMD02028 may not in fact accrue to New Zealand, referring to information not disclosed by AgResearch in the application for "commercial reasons" and to plans announced by AgResearch to seek private investment finance for its development work.

[103] As to economic effects MAdGE referred to a report of the Ministry and Treasury entitled "*Economic Risks and Opportunities for the Release of Genetically Modified Organisms in New Zealand*" released in April 2003 which gave survey results indicating that release of GMOs in New Zealand would have an impact on foreign consumers' purchase intentions with respect to New Zealand commodities. Although the report was concerned with the release of GMOs it was MAdGE's contention that it was not open to the Crown to contend that the significant issues arise only with respect to the commercial "release" of GMOs.

[104] Further MAdGE was concerned with liability for any damage caused by the escape of genetically modified material, a matter under consideration by Government but not a matter within the jurisdiction of the Authority. MAdGE submitted –

> Had the Minister exercised her call in powers some strategic overall management could have been bought to bear to ensure that this important application, namely GMD02028, was properly dealt with.

[105] As to ethical issues MAdGE submitted that the characterisation by the Minister in her affidavit of application GMD02028 as "controversial" carried "an implicit acknowledgement of the ethical considerations involved". MAdGE alluded to the statement by the Royal Commission in its report that in the –

> ... absence of an effective framework for ethical decision making, decisions about the use of bio-technology will be made by default (p.40).

[106] MAdGE further noted that at the time of consideration of application GMD02028 establishment of the Bioethics Council was under way but that –

> Despite the recognition of the importance of the Bioethics Council and of an ethical framework, the Crown officials gave no real consideration to ensuring that ethical guidelines were in place or ethical expertise enlisted for the purposes of GMD02028.

[107] Given the broad definition of "environment" under s.2 of the Act MAdGE submitted that ethical considerations ought properly to have been given serious consideration under s.68(1)(b), and also relied on the additional provision in s.68(1)(e) that the Minister may call in an application if it will have significant effects in an area in which the Authority lacks sufficient knowledge or expertise. That was not confronted, submitted MAdGE. Jonathan Coakley's statement in his affirmation that he –

> knew some of the Authority's members had expertise in ethical issues ...

is inadequate, against a background where the Authority itself acknowledged in the E & R report that it had no method for looking at ethical concerns.

[108] MAdGE was critical of the "process" adopted by the Authority for reviewing applications. The process is not set out in any internal documents, nor had it been

formally agreed with the Minister. The Ministry files did not contain the 2 May 2002 letter from the Authority advising of GMD02028 and enclosing the summary of the application which set the process in train. Mr Vaughan might have initialled the letter of 13 May from the Authority advising that the Authority had verified the application as meeting the information requirements for consideration by the Authority, but that was too late for proper scrutiny to be given to the application since the call in period expired on 22 May 2002 and there was either no or very limited opportunity for any call in to be notified in the Gazette by that late stage. MAdGE submitted that the "process" claimed by the Ministry was quite inadequate given the importance of these matters. There was no agreement with the Minister as to the process, no written record of procedures, no written record of the assessments made or the reasons for them and no advice to the Minister. At best there was "an informal understanding as to what was to happen" and that does not do justice, in fact it ignores the strict approach of the Act, to matters of risk assessment, and means that important policy points have been decided by default.

[109] AgResearch presented submissions on all causes of action in support of the named respondents. In summarising submissions in this judgment I have treated them on an inclusive basis.

[110] For the Minister, counsel submitted that there had been no "failure" by the Minister to consider whether to call in and herself decide AgResearch's application. That she did not do so was due to the fact that the application did not trigger any of the s.68 criteria. Accordingly she did not abdicate her authority nor in the absence of a triggering criterion, was it unreasonable for her not to consider the exercise of her call in powers.

[111] In examining the call in power under s.68, the Crown emphasised that the call in power meant nothing more than that the Minister, because of the potential significance of the effects of the decision, can transfer the power of decision on a specific application from the normal decision maker, the Authority, to the Minister. But the procedure that follows notification of call in is exactly the same as when the Authority is making the decision. The Authority conducts a public inquiry and reports to the Minister. Then the Minister must within 20 working days after

receiving the Authority's report give her decision in writing including reasons (s.71, s.72, s.73). No decision is required from the Minister if she is not proposing to exercise her call in powers and accordingly there is no requirement for reasons unless she decides to call in. There is no appeal from her decision. For while the Minister's decision has the same effect as a decision of the Authority it is not deemed to be a decision of the Authority which would provide a right of appeal under s.126 on a question of law. In that respect the call in provisions of the HSNO Act differ from those in other Acts where a similar scheme operates, e.g. the Resource Management Act 1991 and the Agricultural Compounds and Veterinary Medicines Act 1997. Under the HSNO Act the Authority's report, but not the Minister's decision, can be appealed on a question of law pursuant to s.126.

[112] Neither the HSNO Act nor the other two statutes specify how the Minister is to go about making her decision about whether to call in a particular proposal or application.

[113] The Crown acknowledged that there was no written procedure, nor a procedure that had been formally agreed with the Minister. Nevertheless there was a procedure as set out in the affidavits of Mr Vaughan and Mr Coakley referred in paras [68] to [86] above.

[114] The process, submitted the Crown, results in all applications notified to the Minister by the Authority being screened by Ministry staff. It provides for active monitoring within the tight time constraints of the HSNO Act. It was submitted that the process provides an effective and efficient method of considering applications in relation to call in as well as ongoing monitoring of the Authority by the Ministry.

[115] As confirmed by the Minister's affirmation of 20 May 2003, she is aware of the process and has confidence in it, though of course the Ministry need not be the only source of information that might promote consideration of call in by the Minister. She has many avenues for discerning public opinion and concerns about specific applications. The Minister does not expect to hear from the Ministry about a particular application unless a decision on it would trigger significant effects and in terms of s.68 the Minister is entitled to direct that she will decide the application

only when she considers that it "*will* have significant effects of an economic, environmental, international or health nature or in an area where the Authority lacks knowledge and expertise".

[116] The Crown emphasised that the Authority is a national body considering applications on a national level, that it is a creature of the HSNO Act and in terms of that Act has appointed to it by the Minister persons with the knowledge and expertise to perform the functions required of them by the Act. The Crown noted that while MAdGE requires to see reasons why the Ministry decided that application GMD02028 did not raise significant effects and the report to this effect from the Ministry to the Minister, the HSNO Act requires no such report.

[117] Nevertheless the Crown acknowledged that a responsible process is required by the Ministry as a public body in the performance of its statutory function. The Crown submitted that a responsible process was applied and followed.

[118] As to the second cause of action the Crown submitted that the alleged failure of the Minister to consider whether to call in the application could not be categorised as "perverse" "absurd" or "outrageous" or "in defiance of logic", those being the criteria to establish unreasonableness (see *Wednesbury* and *Wellington City Council v Woolworths*).

[119] In considering whether the alleged failure of the Minister to call in was unreasonable, meaning "outrageous in its defiance of logic" or "so absurb that the Minister must have taken leave of her senses", the Crown submitted that AgResearch's application needed to be placed in context. In 1999 the Government announced in response to the considerable public interest and uncertainty about the topic of genetic modification that an official investigation was warranted. The Royal Commission on genetic modification was established in May 2000 and was required to report back by 1 June 2001. That report date was extended to 27 July 2001. As part of its warrant the Royal Commission was asked to consider and comment on –

> Whether the statutory and regulatory processes controlling genetic modification, genetically modified organisms, and products in New Zealand are adequate to address the strategic outcomes that, in [the Royal Commission's] opinion, are desirable, and whether any legislative,

regulatory, policy, or other changes are needed to enable New Zealand to achieve these outcomes.

[120] The Royal Commission's conclusion on that point was –

> That an appropriate regulatory and institutional framework for the controlled use of genetic modification is already provided by the HSNO Act (p.331 of the Royal Commission's report).

[121] Some recommendations were made for additional controls to make the existing system more robust but the major conclusion of the Royal Commission was –

> ... New Zealand should keep its options open. It would be unwise to turn our back on the potential advantages on offer, but we should proceed carefully, minimising and managing risks.

[122] In relation to cultural, spiritual and ethical issues, the Royal Commission recognised the need to address such issues in the context of new forms of technology and recommended that the grounds for the exercise of the Minister's call in powers be expanded to include significant cultural, spiritual and ethical issues. (This recommendation is included in the Bill now before Parliament – the New Organisms and Other Matters Bill introduced on 29 April 2003).

[123] The Royal Commission also recommended the establishment of Toi te Taiao; the Bioethics Council. It was to act as an advisory body on ethical, social and cultural matters and the use of bio-technology in New Zealand; assess and provide guidelines on bio-technological issues involving significant social, ethical and cultural dimensions; provide an open and transparent consultation process to enable public participation in the Council's activities.

[124] The Royal Commission at p.43 of its report saw the Bioethics Council as a vital forum where issues of national significance were addressed and appropriate guidelines formulated supporting practical outcomes. It would be an expert and independent body on matters of principle and to develop guidelines for ERMA and other bodies.

[125] Particularly in relation to transgenic animals the Royal Commission had this to say in relation to the ethical decision making framework at p.40 –

> We see the question regarding transgenic animals, for example, as one where the Bioethics Council would develop guidelines at a policy level. Case-by-case assessment by ERMA would still be required in order to consider the details specific to each application.

[126] Legislation has followed to implement various aspects of the Royal Commission's report. In particular the 2002 amendment to the HSNO Act assented to on 27 May 2002 extended the voluntary moratorium on release from containment of new genetically modified organisms, to 29 October 2003. It also, relevantly to the application the subject of this proceeding, inserted ss.44A and 45A into the Act including additional matters to be considered and additional controls to be applied to field tests and to developments of GMOs which did not take place in a containment structure.

[127] Also in response to the recommendations of the Royal Commission the Bioethics Council was established in December 2002. Its terms of reference make clear that its role is as a Ministerial advisory committee. As envisaged by the Royal Commission its role does not include involvement in individual applications submitted to the Authority.

[128] In placing AgResearch's application made in May 2002 in the context of these developments the Crown noted that the application was made after the Royal Commission had reported, during the period of the voluntary moratorium, and just prior to the 2002 amendment coming into effect. However, the Crown noted that both the Minister and the Ministry were aware of the 2002 amendment provisions and that AgResearch's application would need to be considered in terms of those provisions. In the Authority's letter to the Minister of 2 May 2002 signed by Bas Walker, Chief Executive of ERMA (which was copied to the Ministry), he states –

> This application will be subject to the provisions of the Genetically Modified Organisms and Restricted Bio-technical Procedures Bill if that Bill is enacted in the form in which it was reported back from the Finance and Expenditure Committee. This is because the proposal includes elements of the development that take place outside of a containment structure. The application acknowledges this.

[129] The Crown submitted that –

> If the Government wished to stop all genetic modification or even genetic modification that used human genes it could have done so by legislation. It did not, and has not, done so.

[130] The Crown noted that neither the voluntary nor the statutory moratorium applied to GMOs in containment or development but primarily to the *release* of GMOs. Nor did the Government's approach to the recommendation for the established of a Bioethics Council seek to defer applications under the HSNO Act until the Bioethics Council was established. But even if the Council had been established when AgResearch's application was made it would not have been the role of the Council to consider or deal with the application. It is a policy body to be engaged with matters of principle.

[131] Both the Minister and the Ministry were well aware of the Royal Commission's report and recommendations, the emerging legislation and the wider background of community concerns about GMOs and in particular the transfer of human genes into other species. The Crown submitted –

> ... there will never be perfect knowledge, but as the Ministry officials are in the midst of legislative and policy development on hazardous substances and new organisms they are well placed to know what is happening on these matters.

[132] In relation to the research report released by the Ministry and Treasury in April 2003, the Crown noted that the report addresses particularly "release" whereas this proceeding and AgResearch's application relate to a "development". Policy development and research in this area is an on-going process. Research on horizontal gene transfer (to which MAdGE addressed particular concerns), is still being undertaken. Questions of liability for adverse environmental or public health effects have not been resolved.

[133] So putting the AgResearch application in context, the Crown submitted –

> ... there is nothing that suggests it was unreasonable for the Minister/Ministry to decide that the application did not trigger any of the s.68 criteria. The application was for development, not release. Parliament had already indicated where its concerns laid through the moratoria. The report by the Royal Commission did not call for an end to genetic

> modification. The Bioethics Council may provide guidance but it will never be involved with a particular application.

[134] In relation to the existing statutory scheme applying to the Minister's call in powers the Crown submitted that the legislation does not provide a great deal of guidance on how the Minister is to decide whether to call in an application; that the Minister has only 15 working days from when ERMA receives the application to publish a notice in the Gazette, which is a restricted time period given that it runs from the time when the Authority (not the Minister) receives the application, and she receives 5-10 applications per month. The Crown submitted that these statutory constraints indicate that Parliament did not expect the Minister or the Ministry on her behalf to undertake a detailed analysis of the application. It would be unreasonable to expect otherwise given the constraints of the legislation.

[135] While MAdGE complains that the application was not given the close scrutiny intended by the Act, it was never intended, and could not be intended, within the 15 working days period allowed, for the close scrutiny which MAdGE requires to be given by the Minister. When an application has significant effects as determined by the Minister which are apparent on the face of the application and from the Ministry's and the Minister's own knowledge, consideration of call in will arise; otherwise it could not apply as the Act does not reasonably enable it to.

[136] Further the Crown submitted the test for "significant effects" is high. It equates, submitted the Crown, with the term "significant national effects" in the Resource Management Act because under the HSNO Act consideration and approval of applications is already conducted at a national level by the Authority, whereas under the Resource Management Act that function is conducted at a regional level. And s.68 triggers the Minister's power of call in only when she considers that a decision on an application "*will* have" significant effects.

[137] It would be unreasonable to expect the Minister to undertaken an expert analysis in respect to each application on its economic, environmental, international and health effects above and beyond what is provided by the applicant (on whom s.40 of the Act places the onus to provide information on "all the possible adverse effects of the organism on the environment") and later verified by the Authority.

The documentation and the Ministry's own knowledge are enough to undertake the initial consideration of whether the effects are such that call in should be considered. It was not unreasonable for the Ministry staff (the alter ego of the Minister) to conclude that AgResearch's application did not meet the threshold requirements of s.68 on the basis of their own knowledge and the information provided.

[138] The Crown further submitted as to process that the Act only requires reasons to be given when call in is decided upon – not an explanation of why an application does not in the Minister's consideration, reach the threshold (while conceding that ideally the Minister, or Ministry on the Minister's behalf, should record its conclusions).

[139] While the AgResearch application GMD02028 may have some new elements that does not give rise to significant effects. Nor are the ethical issues raised by the application, novel. Human genes have been placed in non-human hosts prior to this application. Whether or not ethical issues are included within the definition of "environmental effects" or included within s.68(1)(e) (significant effects in an area in which the Authority lacks sufficient knowledge or experience), the decision reached by the Ministry was that there was nothing about this application that meant that the effects were significant.

[140] Further on a practical level, there is no power for the Minister to defer the application. By calling in the application she can neither defer nor stop it. The Act provides a strict timetable under which the processing of the application must be conducted. If the Minister were to call in, the Authority must consider, inquire and recommend to the Minister. Then the Minister must make her decision having regard to the report and recommendations of the Authority and give her reasons for calling in the application, within 20 working days after receiving the report from the Authority. This process, submitted the Crown, does not contemplate or allow deferral by the Minister for the input of a body such as the Bioethics Council, or for developments in such complex issues as liability for adverse environmental or public health effects of GMOs.

[141] The Crown emphasised that the requirement on MAdGE before the Court could grant the relief sought, is to show that the Ministry's decision defies logic, is absurd and that no reasonable person knowing the same facts would have come to that conclusion. That other parties (including MAdGE) would have reached the different conclusion does not mean that there is anything illogical about the decision made by the Ministry on behalf of the Minister.

[142] Counsel concluded by quoting from the Minister's affirmation –

> Some applications are controversial, as this one relating to transgenic cattle development clearly is. Just because something is controversial does not, however, mean that the Authority should not make a decision on the application.

Discussion

[143] The HSNO Act establishes a comprehensive scheme for preventing or managing the adverse effects of hazardous substances and new organisms. It establishes the Authority, vested with the responsibility for receiving applications made pursuant to the Act, verifying them for compliance with the requirements of the Act, and assessing them pursuant to the procedures in the Act (including public notification and the holding of a public hearing at the discretion of the Authority). The Authority may then approve the application if it is for one of the purposes in s.39(1) of the Act and if, after taking into account all the effects of the organism, the Authority is satisfied that the beneficial effects of having the organism in containment outweigh the adverse effects of the organism should the organism escape, and the Authority is satisfied that the organism can be adequately contained. Otherwise the Authority may decline the application.

[144] On the circumference of this scheme sits the Minister's power to call in applications. The Minister and the Ministry are notified of any application. The Minister then with the assistance of advice from the Ministry (which has the function pursuant to s.31(a) of the Environment Act 1986 to advise the Minister on all aspects of environmental administration), may exercise her call in powers in the limited circumstances specified in s.68.

[145] Section 68 is clearly not a licence for the Minister to become involved in the nuts and bolts of applications. That responsibility is vested in the Authority the members of which are appointed by the Minister for their expertise and experience in the relevant fields of the Authority's responsibility (and they have power to co-opt additional expertise for specific applications). On them the Act confers the responsibility of assessing and determining applications in accordance with the Act, and on them the Minister relies to perform those functions. The s.68 call in power is a power that would be exceptionally used, as has been demonstrated by the experience to date. It has never been exercised under the HSNO Act and a like power under the Resource Management Act 1991 has been exercised only once. It is a power which enables the Minister to intervene if on a public policy level there is a risk that the "big picture" as it affects New Zealand on a national and international level may be overlooked or insufficiently taken into account in relation to a specific application. But because the Act places a clear onus on the applicant to advise of all adverse effects and on the Authority to be satisfied as to the containment and control of adverse effects of any new organism, it will be rare indeed that the Minister determines it is necessary to herself decide an application, rather than the decision being made by the Authority specifically vested with that power and responsibility by the Act.

[146] Thus when the Ministry considers on behalf of the Minister an application notified by the Authority it is concerned with the big picture at a national, and perhaps international public policy level. It would be idle for the Ministry to repeat in any significant respect the detailed consideration of an application required of the Authority. The 15 working days allowed for call in would not permit the close scrutiny required of the Authority, but it would allow serious and responsible inquiry into, and report to the Minister, on a particular effect or aspect which the Ministry considered should or could properly trigger call in. On behalf of the Minister, its obligation is to be mindful of significant effects, economic, environmental, international, health or others outside the Authority's knowledge or experience, and if having justifiable concerns, to advise the Minister to consider her power of call in. In playing its part in the process the Ministry, as the alter ego of the Minister, is entitled to rely on the expertise of the Authority to perform the functions and exercise the discretions vested in it by the Act. It is likely to be a rare instance that

the Authority would receive an application and in particular verify an application, in an area in which it lacks sufficient knowledge or experience to assess and determine it.

[147] It is clear in this case that the Ministry did consider and assess AgResearch's application GMD02028. The process it applied has been criticised, I believe justifiably, by MAdGE to which I shall return shortly. But the affidavits/affirmations of Mr Vaughan and Mr Coakley evidence a general knowledge and understanding of the application and its background, supplemented by the summary of the application provided with the application when notified by the Authority on 2 May 2002, and an assessment by them that it did not raise any of the significant effects specified in s.68 such as would require advice to the Minister to consider exercise of her call in powers. It has to be remembered that the application the Ministry was considering was for development of a GMO. Before there was any issue of release of any GMO that might result from the development, applications for field testing and release would be required, and each stage would need to meet the detailed requirements of the Act if approval were to be gained.

[148] When seen in context it is not surprising nor unreasonable, that the consideration by the Ministry officials on behalf of the Minister of the AgResearch application, did not alert them to significant economic effects which should prompt them to advise the Minister to consider call in. Nor that they did not have particular regard to the economic consequences of New Zealand losing its GE free image in agriculture as pleaded in para (d)(i) of the particulars of the first cause of action in the statement of claim. That is a policy consideration which has engaged much debate and prompted the April 2003 report by the Ministry and Treasury, but such economic effects are not likely to be raised significantly by a development application. Indeed the report concentrates on economic effects flowing from "release" from containment of GMOs.

[149] Further, the officials were aware of the knowledge and expertise of the Authority in relation to the application. The membership of the Authority is known to the Ministry, together with the areas of expertise and experience of the members. The Ministry advises the Minister in relation to appointments. The Committee of the

Authority appointed to determine the application was augmented by the appointment of Manuka Henare specifically to bring the understanding and knowledge of ethical and cultural issues considered to be important in respect of the application. The Ministry officials stated they were satisfied with the knowledge and expertise of the Authority to properly deal with the application when viewed from the perspective of the significant effects listed in s.68. These do not of course include ethical and moral issues particularly referred to in para (d)(ii) of the particulars to the first cause of action in the statement of claim. But assuming the contention of MAdGE is correct that they are included by the s.2 definition of "environment", given the composition of the Authority it is not surprising that the Ministry did not consider in terms of s.68 that there were significant ethical and moral effects which would fall outside the knowledge or expertise of the Authority constituted as it was.

[150] In para (d)(iii) of the particulars to the first cause of action it is pleaded that the Minister did not consider whether applications should have been deferred pending determination by the Government of the issue of liability for adverse environmental or public health effects of new organisms.

[151] Paragraph [111] summarises the process the Act provides in the event that the Minister directs under s.68 that she will decide the application. There is no provision for deferral. The process provided by Part V of the Act follows the Minister's direction in exactly the same way as if the Authority were to determine the application. There are strict time lines culminating with a report by the Authority to the Minister and her decision within 20 days of the report.

[152] It is convenient at this point to refer to para (d) of the particulars to the second cause of action where MAdGE pleads that the Minister was aware of the recommendation of the Royal Commission that a Bioethics Council be established and that such Council should have a particular role to play in relation to transgenic animal applications. Because the Minister had no power to defer the application to await guidelines or other input from the Bioethics Council once established, even if on the basis of advice from the Ministry or from information gathered from other sources, she had considered it appropriate or desirable to do so, it cannot have been

unreasonable of the Minister not to decide to call in the application on that ground. Nor for the Ministry not to have advised her to that effect.

[153] Further, in this case, given that the report of the Authority to the Minister would have followed its decision recommending approval of the application subject to conditions, it is highly unlikely that the Minister would have reached a different decision from the Authority. Indeed in her letter responding to Mr Jon Carapiet dated 2 December 2002 she confirms her confidence in the Authority's ability to carry out its duties under the HSNO Act, as she notes in para 19 of her affirmation.

[154] Under the second cause of action the first three particulars relate to aspects claimed by MAdGE to be novel: that the application was the first generic transgenic application under the Act; the first involving animals since the Royal Commission report; the first to be determined since the 2002 amendment to the HSNO Act. Issues of novelty do not of themselves give rise to grounds for call in under s.68. To the extent that the application raised novel issues (and the Crown and AgResearch do not accept novelty in all respects claimed by MAdGE), the Authority is equipped to inquire, consider and determine the application taking into account the aspects which are novel and which therefore require particular consideration by the Authority in carrying out its functions under the Act. It is relevant that there was a public hearing in respect of the AgResearch application. MAdGE among others made submissions and appeared at the public hearing. There can be no doubt that the issues novel or claimed as novel, were drawn clearly to the attention of the Authority together with the concerns arising from them. That was the body to consider them, and to weigh and balance them in relation to other risks and benefits. It was not unreasonable (meaning perverse, absurd, outrageous) for the Minister not to regard them as giving rise to significant effects under s.68.

[155] Sections 44A and 45A were introduced into the HSNO Act by the 2002 amendment on the recommendation of the Royal Commission. The new sections specifically contemplate and provide for the development of GMOs in containment when the development does not take place in a containment structure. The sections recognise that such developments will occur outside a laboratory situation and specify that additional matters that must be taken into account and additional

controls will be required in relation to these developments, and to field tests. It cannot in my view be considered unreasonable that the Minister did not exercise her discretion to call in an application for a development in conditions specifically contemplated and provided by the new sections. If the legislature had intended that the Minister should intervene as a matter of policy in the first or any such application, then it could have so provided. It did not do so. As with all matters in respect of applications under the HSNO Act, the responsibility for taking into account the additional matters and providing for controls rests with the Authority.

[156] Under para (e) the particulars to the second cause of action refer to public concern over genetic modification in relation to the mixing of human and animal genes. This is certainly not a new matter. It is one of the areas of concern which prompted the appointment of the Royal Commission and its terms of reference. The issue is controversial as the Minister noted in her affirmation. That it is controversial does not provide a ground for call in. It is interesting to note that whereas under the Resource Management Act 1991 one of the factors to which the Minister may have regard in determining call in, is "widespread public concern or interest regarding its actual or likely effect on the environment", there is not like ground under s.68.

[157] Para (f) of the particulars to the second cause of action refers to liability to adverse environmental or public health effects of new organisms being a complex issue requiring urgent consideration by the Government. That is accepted by the Crown. But there is no power to defer. It is not a ground upon which it would have been reasonable for the Minister to exercise her discretion to call in.

Conclusions on first and second causes of action

[158] For all the above reasons my conclusions in respect of the first and second causes of actions are –

a) The Minister did not fail to consider whether she should call in and decide the application under s.68 of the Act.

b) That the Minister did not call in the application pursuant to s.68 of the Act, was not unreasonable.

The Ministry's processes

[159] As stated above, I believe MAdGE has justifiable concerns about the processes of the Ministry in performing its function of advising the Minister in respect of the application. While I have reached the conclusion that there was not a failure to consider AgResearch's application, nor that the Minister acted unreasonably, I consider that the informal processes adopted by the Ministry for dealing with such matters is less than satisfactory. Perhaps the necessity of responding to this proceeding has already alerted the Ministry to the need to adopt a protocol which is clear and responsive to the functions and responsibilities it carries to advise the Minister on such applications. While the Crown initially submitted that the process was one agreed with the Minister it acknowledged that "informal understanding" was a more accurate description. Given the importance of these matters, that in my view is unsatisfactory. A clear protocol is needed, supported by systems within the Ministry to ensure that the protocol is observed and that the Ministry is patently accountable in respect of the process. The Ministry's conclusions should be recorded. Although it must ultimately be a matter for the Ministry and the Minister, I would have thought it desirable that such a protocol would include a report to the Minister tendering the advice of the Ministry in respect of each application, whether or not the advice is to recommend consideration of call in.

Ethical issues

Pleading

[160] The third to sixth causes of action are against ERMA.

[161] The third cause of action pleads –

In approving the application, ERMA failed unlawfully to consider ethical and moral considerations, and to recognise and provide for the maintenance and enhancement of the capacity of people and communities to provide for their own economic, social and cultural well-being.

Particulars

a) ERMA was advised by the ERMA New Zealand Evaluation and Review Report that there was an absence of any structure to evaluate ethical objections.

b) ERMA failed to defer the application until after the Bio Ethics Council had been set up.

c) ERMA purported to deal with ethical objections in the absence of a structure and, in effect, gave the ethical issues no consideration at all.

d) ERMA failed to consider whether it should have commissioned a report or advice from an ethical expert under s.58 of the Act, despite its having determined that it was required to consider ethical issues and despite the requirement in s.5(b) to recognise and provide for social and cultural well-being.

[162] The relief claimed is an order that the decision of ERMA to approve the AgResearch application is unlawful and of no effect.

[163] The response of the Authority is straightforward. The Authority (through the committee appointed to consider the application) considered ethical issues were relevant under the Act and expressly considered them in dealing with the application.

[164] The Authority accepted at p.38 of its decision that ethical issues were matters to be considered. It stated –

> Although the Act does not directly identify ethical issues as matters to be considered, there is a presumption that they should be both in the wording of

s.5(b) and the definition of "environment" in s.2. In addition, the Royal Commission on genetic modification noted at p.24 and 38 of their report that ss.5, 6 and 8 of HSNO implies certain values that enable ethical decision making.

Submissions

[165] MAdGE recognised in submissions that while weight to be given to mandatory relevant considerations is a matter for the decision maker, decisions can be reviewed and set aside for "no weight" as opposed to "wrong weight". MAdGE submitted that the Authority attempted to deal with ethical issues but in substance gave no weight at all to these important factors. MAdGE referred to a statement in the E & R report at p.51 –

> ... that in the absence of a proper structure for doing so, it is extremely difficult to decide how far such ethical points of view should be accepted and what weight they should be given in decision-making.

[166] The E & R report also observed at p.51 –

> While a number of submitters have expressed concerns from an ethical standpoint, the concerns represent personal opinions rather that representations based on a particular framework of reasoning, or on a properly surveyed or documented body of opinion. Personal opinions of this type are difficult to take account of because there is no way of linking them to wider opinions.

[167] MAdGE submitted that because of such concerns and because of submissions that the application should be deferred pending establishment of the Bioethics Council, the Authority should have given serious consideration to seeking further information under s.58 of the Act about these matters.

[168] Further that there was no real engagement with one of the fundamental ethical objections to genetic engineering, as discussed by Susan Watson in her paper, namely the threat that genetic engineering imposes for humanity's sense of dignity and autonomy. The reference is to an article "Bioethics: Too Important for the Too-Hard Basket" Susan Watson, Senior Lecturer, School of Law, University of Auckland presented to the Bio-technology Law Conference in February 2003 exhibited to an affidavit of Susan Watson sworn 11 March 2003. Susan Watson's affidavit states that she takes no particular position in the proceedings but believes

that ethical issues must be addressed as part of the important on-going debate about genetic modification. I note that this article had not been published at the time application GMD02028 was considered by the Authority.

[169] MAdGE's concerns on this aspect are expressed in the affidavit of Katrina Woodd dated 13 January 2003 at para 8 –

> MAdGE believes that Government made a good start in setting up the Royal Commission but has since failed to implement the recommendations before allowing applications such as the one the subject of these proceedings to proceed. In particular, MAdGE is not satisfied that the ethical issues which arise in respect of experiments involving the insertion of human genes into other mammals and the subsequent release of those other mammals into the contained environment or the environment generally have been addressed in a meaningful way. MAdGE believes that it is fundamental that there be an informed ethical debate in relation to applications to create GMOs, particularly those involving human genes.

Discussion

[170] Having accepted the need to consider ethical issues the Authority in its decision deals with four specific ethical issues raised by submitters opposed to genetic modification –

a) Use of companion animals for genetic modification experiments is unethical;

b) Concerns about the entry of cattle products containing human genes into the food chain;

c) Genetic modification is against the teachings of the bible; and

d) Animal welfare issues.

[171] It considered each of those issues in its decision. At p.47 it states –

> The Committee recognises the high level of public concern over the appropriateness of genetic modification as a technology and the modification of food-producing animals in particular. However, the Committee does not

> consider that such ethical concerns are overriding in the circumstances of this application.

[172] It is clear the Committee did consider ethical issues which they identified as relevant.

[173] It did not consider that further expert opinion was necessary. Kevin John Currie, manager operations with ERMA, whose evidence is confirmed by Colin David Mantell on behalf of the Committee, states at p.33 of his affirmation made on 9 May 2003 –

> The Committee had the ability, if it wished, to seek an expert opinion on any issues including ethical issues. However that was not necessary. As noted at p.51 of the E & R report, the Authority had considered several previous applications involving broadly comparable issues, and the Committee included members with experience in dealing with ethical matters and scientific medical, political, anthropological and Maori contexts.

[174] In short, the Committee turned its mind to the matter but considered that it had within its membership the experience and expertise to give adequate consideration to ethical issues relevant to the application before it.

[175] I have already referred to the establishment of the Bioethics Council in the context of this application (refer paras [123] to [127] and [151] to [152]. As Mr Currie notes in his affirmation, there is no power in the Act for the Authority to defer a decision on the application until the Bioethics Council was established, even if it had thought it relevant to do so, and –

> ... the Committee could see no particular merit in awaiting the establishment of the Council ... The Royal Commission noted that while the proposed Bioethics Council would develop policy guidelines ERMA New Zealand should continue to consider details specific to each application .. This has subsequently been reflected in the Terms of Reference for the Bioethics Council.

[176] When MAdGE criticises the Authority for failing to come to grips with "fundamental ethical objections to genetic engineering", it reverts to a perspective which it and other interested parties have presented in a number of forums and will no doubt continue to present, in what Susan Watson describes as the important on-going debate about genetic modification. But the reality is that the HSNO Act

specifically provides a system for the approval of applications for development, field testing and release, of GMOs. The structure of the HSNO Act was generally approved and confirmed by the Royal Commission. If Parliament had considered ethical perspectives to be of such significance that applications for development of GMOs should be deferred until the on-going debate had been concluded (if ever it will be), then it could have so provided, possibly by way of a moratorium as is the case with the release of new organisms. It has not done so. The Authority is required by the HSNO Act to receive, consider, process and determine applications. It has acknowledged the need to consider ethical issues in the context of a particular application, and did so in respect of this application. It is not required by the "recognise and provide for" provision of s.5 in relation to the principle of economic, social and cultural wellbeing of people and communities, nor by any other provision of the Act, to give greater significance to the ethical and moral concerns of MAdGE or any party making submissions, than to other factors it must weigh in its overall evaluation. It cannot be expected in the context of a particular application to embark on a consideration of the public policy issues involved in fundamental ethical objections to genetic engineering generally, which have been presented in wider forums and will inevitably be the subject of on-going debate.

Conclusions on third cause of action

[177] I conclude that the Authority did not unlawfully fail to consider ethical and moral considerations, nor did it fail to apply the principles in s.5 of the Act in reaching its decision on the application. The Authority in carrying out its statutory functions as prescribed by the HSNO Act cannot be expected to remedy what MAdGE perceives is a failure by Government to extend the ethical debate as MAdGE considers it should.

All the possible adverse effects of the organism on the environment – s.40(2)(a)(v)

Pleading

[178] The fourth cause of action against ERMA pleads –

ERMA determined that the burden borne by AgResearch, as applicant for approval, to specify in its application "all the possible adverse effects of the organism on the environment" (s.40(2)(a)(v)) was discharged in circumstances where a bare level of information had been provided by AgResearch in the application.

[179] The determination by ERMA was one based on material error of law.

Particulars

a) ERMA determined that the broadness and lack of specificity of the organism description in the AgResearch application, and the fact that organisms were to be outside rather than in a contained laboratory, made assessment of all possible adverse effect on the environment very difficult.

b) ERMA determined that on a strict interpretation of the requirements AgResearch had "possibly failed" to identify all possible adverse effects. ERMA, nevertheless, purported to apply a standard of reasonableness.

c) ERMA then determined that despite a bare level of information being provided "in some respects", the AgResearch application was a valid one to be considered.

[180] The relief sought is an order that the decision of the Authority to approve the AgResearch application is unlawful and of no effect.

[181] As I understand the thrust of the applicant's argument it was that if generic applications are permitted by the HSNO Act then the requirement of s.40(2)(a)(v)

must be considered in that light. If they are not, then this issue does not require consideration because compliance with s.40(2)(a)(v) would then be in respect of a different and more specific application.

[182] I turn therefore to consider the fifth cause of action.

Jurisdiction of ERMA to consider a generic application

Pleading

[183] The fifth cause of action pleads –

ERMA determined that there was nothing in the Act to preclude it considering and approving a generic application for the development of a new organism.

ERMA's determination was one based on material error of law in that ERMA does not have jurisdiction under the Act to consider and approve generic applications for the development of a new organism.

[184] ERMA determined that there was a sufficient level of information in the application regarding –

a) the identification of the organism; (S.40(2)(a)(i))

b) the description of the project and the experimental procedures to be used; (s.40(2)(a)(ii))

c) the details of the biological material to be used; and (s.40(2)(a)(iii))

d) the expression of foreign nucleic acid material; (s.40(2)(a)(iv))

to meet the requirements of s.40(2)(a) and s.20(2)(b) of the Act.

ERMA's determination was one based on material error of law in that there was not sufficient information in the application to satisfy the legal requirements of s.40(2)(a) and s.20(2)(b) of the Act.

[185] The relief sought is an order that the decision of ERMA to approve the AgResearch application is unlawful and of no effect; and a declaration that ERMA has no jurisdiction under the Act to consider and approve a generic application.

[186] The response of ERMA is that there is nothing in the Act to preclude a generic application provided the application is in an approved form and there is sufficient information to meet the requirements of s.40(2)(a) as set out in (a) to (d) above and to uniquely identify the organism as required by s.20(2)(b).

The decision

[187] The Authority concluded that there was sufficient information to meet the requirements of the Act for the application to be considered and determined (p.10-12 of the decision).

[188] The Authority observed that there is a distinction between the level of information required to determine the validity of an application, and the information required to assess and evaluate all adverse and beneficial effects to determine whether an approval with controls can be granted.

[189] The Authority analysed the information provided by AgResearch in terms of the requirements of s.40(2)(a).

[190] In relation to subparagraph (i) the identification of the organism, the decision states (p.11) –

> The host organism is clearly cattle but individual animals may contain a range of potential modifications. The precise modifications can be specified before individual animals are created because the genetic construct introduced will be able to be precisely described.

[191] In relation to subparagraph (ii), the description of the project and the experimental procedures to be used the Authority states (p.11) –

> The applicant gives experimental procedures for each step (a) to (f). The application notes that there are two broad aims of the application – some proteins will be expressed in milk and other genes will be introduced to study gene function in cattle. The Committee noted that s.40 is not specific on how much information is required but were satisfied this requirement was sufficiently met.

[192] In relation to subparagraph (iii), the details of biological material to be used, the Authority states (p.11) –

> Details of the biological material were provided in Appendix 1 of the application, describing the types of genetic elements that would be used in the vector. Sources of some elements are not always specifically identified, but the functions and purposes are ... Some bounds are provided in that only well characterised sequences can be introduced into the cattle. The Committee accepted that there was sufficient information provided, although with reservations about the potential to use unspecified source species for some sequences.

[193] In relation to subparagraphs (iv) and (v) the decision expresses reservations about the level of information provided (which was the subject of considerable focus by MAdGE and those who gave expert evidence for the applicant).

[194] As to the information required by subparagraph (iv) on the expression of foreign nucleic acid material the decision states –

> The Committee was of the view that the information on the expression of foreign DNA was barely adequate. However it was satisfied that the legal requirements were met sufficiently to allow the application to be considered.

[195] As to subparagraph (v) the decision states –

> The requirement in the Act for information on "all possible adverse effects of the organism on the environment" sets a high standard. The application addressed adverse effects to some extent and the E & R report discussed potential adverse effects not covered by the applicant.
>
> The Committee was of the view that the broadness and lack of specificity of the organism description and the fact the organisms were to be outside rather than in a contained laboratory made assessment of all possible adverse effects on the environment very difficult. On a strict interpretation of the requirements, AgResearch had possibly failed to identify all possible adverse effects. However, the Committee acknowledged that a standard of reasonableness should be applied when assessing the extent to which

identification of adverse effects was required. On this basis it was decided that on balance the application could be regarded as valid.

[196] The Committee concluded (p.12) -

> Therefore while a bare level of information had been provided in some respects, the Committee concluded there was a valid application to be considered.

Submissions

[197] What is meant by a generic application? The term is not defined in the Act. MAdGE submitted that the application was not framed in terms of a *single* GMO, but rather sought blanket approval on a so called "project basis" for the development of a range of genetically modification cattle which included the deletion from and/or insertion into these cattle of a wide variety of genes from sheep, goat, deer and mice and copy genes from humans.

[198] The Authority submitted that phrases such as "blanket application" or "project-based application" are not apposite to describe application GMD02028. The organism or organisms are always the subject of the application. In this particular application an unspecified number of potential organisms are the subject of the application rather than a single organism, or three organisms as in the *Bleakley* case where the application sought approval for field testing of three constructs designed to affect milk. There is nothing in the Act that prohibits one application from covering several modifications of an organism provided that the risks associated with the process and resulting modified organisms can be properly assessed. There is nothing in the definition of "identification" in s.2 that inherently restricts an application to modification of one single organism or disallows a generic application. There are, it was submitted, practical reasons for flexibility, and applicants are entitled to be given reasonable latitude in deciding how to frame their applications.

Discussion

[199] Identification is defined in s.2 of the Act as follows –

"Identification" means the provision of any information about a substance or organism which—

(a) Clearly identifies the chemical or biological nature of the substance or organism.

(b) Specifies the nature and degree or type of hazard intrinsic to the substance or organism.

(c), (d) and (e) refer only to hazardous substances.

[200] Whether an organism has been "identified" in terms of the definition will inevitably involve expert assessment. That assessment is required to be made by the Authority applying the expertise and experience of its members supplemented by any further information it decides to seek pursuant to s.58 (the Authority may commission a report or seek advice from any person on any matters raised in relation to the application, including a review of any information provided by the applicant).

[201] The Authority starts with the information provided by the applicant to satisfy the requirement for identification in terms of the definition, may seek external expert opinion to review or evaluate that information, and then must reach its own decision as to whether the information provided sufficiently identifies the application to enable it to be considered by the Authority. In this case the Authority determined that the information was sufficient, though in some respects, "barely adequate". But the Authority correctly identified that the level of information required before it could consider the application, and the level of information it might seek or use in order properly to evaluate all adverse and beneficial effects arising from the application in order eventually to determine whether approval should be given subject to controls, are two different steps and may require two different levels of information.

[202] Professor Mantell a member of the Committee states in his affidavit –

> While we were of the view that there was sufficient information to meet the threshold requirements for a valid application under s.40(2)(a) (as noted on p.11 of the decision) and s.20(2) (on p.12) that was only a starting point. Analysis and the application of judgment by Committee members followed. The process we followed, in simple terms, was in two stages. First we refined the organism description to be certain of the boundaries to the range of organisms that could fall within it and, in this way to exclude risks wherever possible. Secondly we sought to manage remaining risks and uncertainties by the imposition of controls.

[203] The refinement involved reducing the scope of the organism description so that modification could be made by deletion and/or insertion of a *single* gene only (with an exception for development of immunoglobulins which may require the insertion of two genes). With the boundaries thus refined the Authority was satisfied that there was sufficient information to describe and identify the Tg organism notwithstanding that the individual transgene would vary.

[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 the Authority 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 the Authority as to whether the application fulfilled the statutory requirements for it to be *considered* by the Authority. That the Authority 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.

[205] Although proposed legislation is not relevant to the interpretation of current law (JS Burrows, Statute Law of New Zealand, third ed, LexisNexis Wellington, pp.398-400) because MAdGE referred to the New Organisms and Other Matters Bill 2003 presently before Parliament in support of its submission that the Act does not permit applications on a "project basis" I will briefly refer to it. The Bill would insert two new sections into the HSNO Act to –

> Streamline the process of approving low risk genetic modification work within contained laboratories by providing for approval of such modifications on a *project* rather than an *organism* basis. (Italics provided)

[206] The amendment would limit the information required under s.42 for an application to develop a new organism in containment where the application describes "a project for the development of genetically modified organisms" and fits

the low-risk criteria, to the identity of the host organisms, and the nature and range of the proposed genetic modifications.

[207] MAdGE submitted that in these circumstances any change to allow project-based applications for development in outdoor containment remains a matter for the legislature.

[208] "Project" does not appear to be defined but the explanatory note seems to contemplate that the modifications will not be on an organism basis. The AgResearch application is on an organism basis, albeit in relation to a range of modifications. I doubt that the proposed amendment adds anything to the understanding of what is a generic application. It is aimed at streamlining an existing process for addressing low-risk genetic modifications.

Conclusion on fourth cause of action

[209] I conclude that the Authority had jurisdiction under the Act to consider and approve AgResearch's application for the development of new organisms on a generic basis, and that the level of information required to sufficiently identify the organism for the Authority to consider the application was a matter properly for assessment by the Authority.

Development v field test

Pleading

[210] MAdGE pleads that ERMAs determination that the application was for a development rather than a field test was a material error of law. The statement of claim pleads as the sixth cause of action –

ERMA determined, in the face of objections from submitters, that steps (e) and (f) of the application could be considered as part of an application for the development of a new (genetically modified) organism in containment under s.40(1)(b), rather than as

an application to field test a new (genetically modified) organism in containment under s.40(1)(c) of the Act.

[211] ERMA's determination was one based on material error of law in that steps (e) and (f) of the application comprise matters that cannot be considered and approved under an application for the development of a new organism in containment under the Act.

Particulars

a) Stages (e) and (f) are identical in nature (albeit with different genetic modifications in the capital concerned) to an earlier application (application GMF98009) that was submitted by AgResearch and approved by ERMA as an application to field test a new organism in containment pursuant to s.40(1)(c) of the Act.

b) The creation of a genetically modified embryo constitutes the development of a new (genetically modified) organism within the meaning of the Act.

c) The subsequent implanting of a genetically modified embryo in a surrogate cow, the generation of live offspring from those embryos and the checking of gene stability through reproduction (being stages (e) and (f) of the application) constitute a trial of the effects of the new organism (i.e. the genetically modified embryo) under conditions similar to those of the environment and to which the organism is likely to be released within the meaning of the term "field test" in s.2(1) of the Act.

d) No genetic modifications will take place under (f) of the application.

[212] ERMA erroneously determined that for an application to be a field test within the meaning of the Act it must involve the carrying on of trials that involve "research procedures aimed at providing statistically valid results about the effects of the organism (including animal or herd performance)".

[213] The relief sought is an order that the decision of the Authority to approve stages (e) and (f) of the AgResearch application is unlawful and of no effect.

[214] The Authority submitted that where experimental procedures cease to be a "development" and become a "field test" is a matter of scientific judgment. The Authority is the appropriate body to make that judgment. It did not exceed its jurisdiction in so doing.

The decision

[215] This issue together with the question of its jurisdiction to consider a generic application was the subject of a preliminary hearing by the Authority. At the conclusion of that hearing the Authority adjourned to hear and consider the submissions on the merits of the application and presented its determinations on all aspects in the decision.

[216] At issue are stages (e) and (f) of the application –

e) The generation of live offspring from cultured embryos.

f) The checking of gene stability through reproduction.

[217] Two definitions in s.2 of the HSNO Act are involved, the definition of "develop" and the definition of "field test" which are as follows –

> "Develop" in relation to organisms, means genetic modification of any organism; but does not include field testing.
>
> "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 trials; and includes large-scale fermentation of micro-organisms.

[218] The decision states that the view of the Committee is that a "trial", in the context of the HSNO definition of "field test", involves research procedures aimed at

providing statistically valid results about the effects of the organism (including animal and herd performance).

[219] To ensure the application does not stray from the confines of a development into a field test, the Committee imposes restrictions on breeding to prevent additional increase in numbers of lines of genetically modified cattle, thereby precluding statistically valid research on the effects of the organism.

[220] The decision states at p.9 –

> In reference to stage (f) the Committee was satisfied that milking is necessary to demonstrate expression of the therapeutic proteins in milk, and that some breeding is reasonable to determine which construct shows stable inheritance. However, the Committee accepts that step (f) has elements of examining the effects of the organism. Since "develop" does not include field testing, and field testing was not applied for or considered, it is essential to set boundaries on this development application to ensure that it does not include field testing.

[221] The decision concludes –

> ... the Committee was satisfied that steps (e) and (f) are part of the investigative process of establishing whether the modifications give rise to expression of therapeutic proteins or alterations of the bovine genome. Therefore the application could be considered as a development, provided breeding restrictions ensure the applicant does not increase, beyond that necessary for development, the number of animals of a particular construct.

Submissions

[222] MAdGE submitted that both stage (e) which involves the gestation and rearing of transgenic calves, and stage (f) which involves a reproduction of genetically modified cattle in an outdoor environment, i.e. whether genetically modified cattle will reproduce naturally in their normal environment, and the expression and testing of milk produced by those cattle, take matters beyond development and must comprise a field test. This is abundantly clear, submitted MAdGE, because at stages (e) and (f) genetic modification of the embryo has been completed. Genetic modification of any organism is a critical component of the definition of "develop" and therefore the process has proceeded from the development to the field testing stage.

[223] MAdGE referred to the view of the Royal Commission that the grazing of commercially modified animals such as sheep or cows in paddocks in circumstances where the research involves the whole organism is a field test (Royal Commission report p.113 at para 45).

[224] MAdGE further submitted that there are important distinctions between the treatment of applications to develop and applications to field test in terms of process, namely -

a) Public notifications of applications to field test are mandatory (s.53(1)(d); and

b) Applications to field test require disclosure of the precise genetic modifications to be tested (s.40(2)(b)(iii).

[225] MAdGE noted that the three applications at issue in the *Bleakley* case under application GMS98009 were for field tests though in respect of very similar processes to those in (e) and (f) of GMD02028.

Discussion

[226] Since application GMF98009 the 2002 amendment has specifically provided in ss.44A and 45A for development in containment but outside a containment structure, i.e. outdoors. The Authority is required to consider additional matters and the inclusion of controls which apply equally to developments outside containment structures and to field tests.

[227] The decision states at p.9 –

> Thus because a development and a field test can equally be carried on in outdoors containment as is expressly provided in ss.44A and 45A, *where* the experimental work is carried out will not necessarily be a determining factor.

[228] While steps (e) and (f) have some aspects in common with a field test, e.g. outdoor containment, those aspects do not automatically exclude them from the definition of development and thereby place them within the definition of field test.

Dr Atkinson the general manager of science at AgResearch who gave evidence before the Committee, says in his affidavit sworn 12 May 2003 –

> If we were field testing the cattle, we would be farming a known developed genetic modification in stable Tg-cows under much less controlled conditions to determine the effects of the organism under "release-like" conditions (such as normal breeding conditions in cycles to maximise production and reduce costs) ... under a "field test" we would not expect to have the degree of containment as we have for this development work. For a field test the experimental conditions would be more similar to those under which the Tg cattle are likely to be released – a commercial farm context.

That observation is not inconsistent with the observation of the Royal Commission referred to at para [223] above. Nor is it significant that application GMD98009 was framed as an application for field tests, particularly as it preceded the new ss.44A and 45A which specifically contemplate developments in containment outdoors.

[229] Further, in the circumstances of application GMD02028 there is little material difference in steps (e) and (f) being treated as part of the development application rather than as a field test. Both categories are treated identically in relation to containment under ss.44A and 45A. The application was publicly notified. So there is little to differentiate treatment under the two categories, except that if steps (e) and (f) were the subject of a field test application it would be made at a later stage and would include information pursuant to s.40(2)(b)(iii) as to the genetic modifications of the organism to be tested. That information will be produced by a successful development stage.

[230] I do not consider the requirement in s.40(2)(b)(iii) does more than reflect the place of field testing in the cycle of approvals required under the HSNO Act. Once the development stage has been successfully completed, the GMO to be field tested will be known. The Authority will need information about it, clearly information that could not be advised in relation to a development application which precedes the proposed genetic modification/s. The requirement does not impose a "higher" level of information for field tests, as MAdGE submitted in support of its contention that stages (e) and (f) should be the subject of a field test application, merely a different requirement which reflects the stage of the process at which the application is made.

[231] The s.7 precautionary approach which requires caution in managing adverse effects where there is scientific and technical uncertainty about those effects (to which MAdGE frequently alluded in submissions) would seem to me to favour treatment of an application as a development application where in terms of scientific judgment the process under consideration was on the cusp, because the applicant would need to return to the Authority with a field test application followed by a release application, rather than proceeding immediately to a release application following successful field testing. In this way the oversight and control able to be exercised by the Authority is enhanced.

[232] The definition of "genetically modified organism" does not limit the modification process strictly to the in vitro modification stage. A "genetically modified organism" means –

> ... any organism in which the genes or other genetically material –
>
> (a) Have been modified by in vitro techniques; or
>
> (b) Are inherited or otherwise derived, through any number of replications, from any genes or other genetic material which has been modified by in vitro techniques.

[233] There is conflicting scientific opinion as to whether genetic modification would continue in stages (e) and (f). Opinion for AgResearch is that it would. Opinion for MAdGE disagrees. While it is clear that at the time an application to field test is made, a GMO has been produced which is to be the subject of trials, precisely when that GMO has been finally created by the development process will often be the subject of scientific judgment. That is not a matter for this Court to determine. The Authority was aware of the conflicting opinion. It was required to make the judgment.

[234] Where "trials" are being conducted on the effects of the GMO as distinct from an investigation or test as part of the development process then the application will be for a field test. The Authority defined a trial in the context of the HSNO definition of field test as involving research procedures aimed at providing statistically valid results about the effects of the organism (including animal or herd performance). Thus a field test is defined in terms of **purpose**.

[235] Because there are likely to be some features in common in a development and a field test, where a development ends and a field test begins will often be a matter of judgment. The Authority recognised that the examination of the effects of an organism may legitimately be part of its development. The numbers of items involved in the trial will be relevant but not necessarily determinative, for the numbers required for statistically valid results will vary depending on the organism and the trials to be conducted. While the place where the trials are to be conducted will not be determinative (for reasons given above), it will usually be that field tests are carried out in release like conditions since the field testing will often precede an application under the HSNO Act for approval to release from containment. These are factors, certainly not exclusive factors, which will weigh with the Authority as the expert body required to make the judgment as to the *purpose* of the tests on the GMO, in determining whether a given step is properly part of a development or a field test.

Conclusions

[236] I accept the submission for the Authority that the precise point at which experimental procedures become "field testing" is a matter of scientific judgment. The Authority was aware of conflicting scientific opinion and of the views espoused by MAdGE. The Authority made that judgment. It is the body with expertise and the responsibility under the HSNO Act to make such judgments. It did not exceed its jurisdiction in so doing.

Adverse effects s.40(2)(a)(iv) continued

[237] I return now to the fourth cause of action that the determination by the Authority that the burden borne by AgResearch as applicant for approval, to specify in its application "all the possible adverse effects of the organism on the environment" (s.40)(2)(a)(v)) was discharged in circumstances where a bare level of information had been provided by AgResearch in the application, was based on material error of law.

[238] This pleading will be considered against the background that AgResearch was entitled to make and the Authority was entitled to receive, a generic application.

Submissions

[239] MAdGE submitted that all effects for each GMO that is produced, must be able to be carefully considered by the Authority when it is carrying out its statutory functions including in particular the requirements in ss.44A and 45A of the Act, and the detailed process of identifying, assessing, evaluating and weighing risks, costs and benefits required by the Methodology order. That, submitted MAdGE, is simply not possible when the organisms themselves are not identified at the time the Authority's approval is required. Accordingly an error of law must arise.

[240] MAdGE's submissions under this cause of action pick up the fifth cause of action that there was no jurisdiction for the Authority to consider a generic application. Because of the breadth of the scope of the application it was not possible for AgResearch to specify all the possible adverse effects of the organism on the environment as required by s.40(2)(a)(v). That necessarily led to a lowering of the threshold for the consideration of possible adverse effects.

[241] MAdGE's concerns under this cause of action are usefully summarised in an affidavit of Judith Anne Carman, Affiliate Senior Lecturer in the Department of Public Health at the University of Adelaide, South Australia. She states at para 7 –

> At p.12 of its decision ERMA complains about the lack of information contained in the AgResearch application by stating "a bare minimum level of information had been provided in some respects". ERMA also notes that the broadness and lack of specificity of the organism description, and the fact that the organisms were to be outside rather than in a contained laboratory, made assessment of all possible adverse effects on the environment very difficult. However, despite registering those concerns, ERMA then decided that they had sufficient information, expertise and knowledge, not only to actually assess the risks but to conclude that the benefits outweighed the risks and the cost (p.2).
>
> Our understanding is that an application for approval to develop a genetically modified organism (in this case, of course, AgResearch) is required to provide information on all the possible adverse effects of the organism on the environment.

> From a scientific perspective, we cannot understand how ERMA can have concluded that AgResearch had met this burden in circumstances where it was complaining that a bare minimum level of information had been provided and where the broadness and lack of specificity of the organism description essentially meant that an assessment of all possible adverse effects was not really achievable. In our view, this application required a very clear understanding of the risks arising from HGT and that ERMA's consideration of the possible risks arising from this issue is seriously wanting. We believe that ERMA had not properly informed itself on this issue. We believe it was incumbent on the applicant, AgResearch, to have provided full information on this important issue in the first instance.

[242] The Authority and AgResearch responded that the phrase "all the possible adverse effects" of an organism –

> ... cannot be interpreted to include adverse effects which even with the use of utmost due diligence could not have been predicted according to the knowledge available at the time. That is an impossibility and would lead to absurdity.

[243] Parliament could not have intended an absurdity. Parliament is presumed to legislate in a manner that produces a practical, workable and sensible approach. Counsel referred to *R v Salmon* [1992] 3 NZLR 8 where Cooke P delivering the judgment of the Court of Appeal said at p.13 –

> In many cases this Court has emphasised the importance of a practical and realistic interpretation of Acts of Parliament. In cases of ambiguity or hiatus they should be interpreted so as to be made to work ... statutory powers must always be read in the light of the policy and objects of the conferring Act. If authority for that proposition be needed it is not necessary to go beyond *Tadfield v Ministry of Agriculture, Fisheries and Food* [1968] AC 997.

[244] Counsel submitted that it is not for this Court on an application for judicial review to delve into the question whether AgResearch did specify all the possible adverse effects of the organism on the environment and whether those effects were properly considered by the Authority (although AgResearch maintains that adverse effects raised by the evidence of MAdGE filed in this proceeding have been addressed by AgResearch).

[245] Further the Authority submitted that while s.40(2)(a)(v) clearly and firmly puts the initial onus on the applicant to put the Authority in the best possible position of knowledge in relation to "all the possible adverse effects of the organism on the

environment", the Authority then brings to bear its expertise and experience in weighing the evidence and making its judgment. While it is entitled to be provided with the best possible information by the applicant who is the party in the best position to know, it is not constrained in its deliberations by that information.

[246] It is not for the Court to weigh the merits of expert evidence in a review application; it is enough that a proper process has been followed. Counsel referred to Ronald Young J in *Smithkline Beecham (NZ) Ltd & Anor v Minister of Health & Ors* (unreported High Court Wellington, CP.49/02) at para [80] –

> This Court's function is not to rule on the science. The important point is that Medface, MAAC and Dr Boyd have considered all the plaintiffs' scientific propositions and have a credible view of the science by relevantly qualified scientists. They have considered and rejected on scientific grounds the plaintiffs' views on safety and efficacy and related matters.

[247] In relation to competing scientific opinion, at para [82][g] –

> Medface and MAAC say one bio-equivalent study is sufficient to assess bio-equivalence and reach conclusions. The plaintiffs' scientists say it is not. This is a matter of scientific opinion and not this Court. Medface say that they assess bio-equivalence on international standards. This decision is not susceptible to a review by the Court.

[248] That case, like this, involved an application for judicial review of a decision of an expert body (a delegate of the Minister of Health and the Ministry of Health), to approve a drug. A number of grounds of review were dismissed, the Court declining to enter upon the merits of the scientific evidence.

[249] AgResearch noted that the Authority has a specific statutory role in considering submissions and scientific evidence and in determining disputes in the evidence. The Authority must follow prescribed criteria in evaluating and determining risk of adverse effects (refer the methodology order). The criteria in the Methodology order for assessing risks and weighing these against benefits, were complied with in the Authority's decision. The Authority's findings should therefore not be open to review on their merits.

Discussion

[250] This cause of action does not raise the issue of whether the Authority itself properly identified and considered all relevant adverse effects. I understand from submissions for MAdGE that the several affidavits filed by MAdGE containing scientific opinion on adverse risks claimed not to have been considered or wrongly determined by the Authority – Wills, Carman, MacGregor and Gibbs – were to demonstrate that because, as MAdGE contends, the Authority proceeded on a bare level of information provided by AgResearch pursuant to s.40(2)(a)(v), the Authority lowered the threshold for its own consideration of adverse effects. The affidavits containing scientific opinion are said to demonstrate that the lack of full information from AgResearch did or could have made a difference. Of course the scientific evidence tendered by MAdGE was countered in affidavits filed by the Authority and AgResearch – Currie, Mantell, Hannah, Atkinson, Conner and Bellamy. Predictably there is a difference of scientific opinion.

[251] This case is not about resolving differences in scientific opinion as I made clear at the outset of this judgment in para [2]. The Authority is an expert body constituted by statute for the purpose of determining applications under the HSNO Act. It is the proper body to consider and weigh evidence. The scientific evidence before the Court is largely irrelevant (refer *Roussel Uclaf Australia Pty Ltd v Pharmaceutical Management Agency Ltd* [1997] 1 NZLR 650, 658).

[252] The Authority dealt with the matter of the information on adverse effects in this way at p.12 of its decision –

> The requirement in the Act for information on "all possible adverse effects of the organism on the environment" sets a high standard. The application addressed adverse effects to some extent and the E & R report discussed potential adverse effects not covered by the applicant.
>
> The Committee was of the view that the broadness and lack of specificity of the organism description and the fact that the organisms were to be outside rather than in a contained laboratory made assessment of all possible adverse effects on the environment very difficult. On a strict interpretation of the requirements, AgResearch had possibly failed to identify all possible adverse effects. However, the Committee acknowledged that a standard of reasonableness should be applied when assessing the extent to which

> identification of adverse effects was required. On this basis it was decided that on balance the application could be regarded as valid.
>
> Therefore, while a bare minimum level of information had been provided in some respects, the Committee concluded that this was a valid application to be considered.

[253] The interpretation of s.40(2)(a)(v) is to be approached with two principles of statutory interpretation clearly in mind –

a) The meaning of a statutory provision is to be ascertained from the text, in the light of the Act's purpose (s.5 Interpretation Act 1999);

b) Parliament is presumed to legislate in a manner that produces a practical, workable and sensible approach (*R v Salmond*: *Nunns v Licensing Control Commission* [1967] NZLR 730 (CA).

[254] The requirement on the applicant pursuant to s.40(2)(a)(v) is very broad. The briefest consideration of the broad definitions of "environment" and in turn "amenity values" and "natural and physical resources" referred to in the definition of "environment" indicate the almost indefinite scope of the obligation imposed on the applicant. Further, "effect" is very broadly defined in s.2 of the Act to include –

(a) Any potential or probable effect; and

(b) Any positive or adverse effect; and

(c) Any temporary or permanent effect; and

(d) Any past, present or future effects; and

(e) Any acute or chronic effect; and

(f) Any cumulative effect which arises over time or in combination with other effects.

[255] In *Canterbury Regional Council v Newman* [2002] 1 NZLR 289 the Court of Appeal at para [78] stated –

> "Effects" taken in isolation can extend to a chain of consequences of almost infinite length ... The word is not to be taken in isolation, and is not to be allowed ridiculous scope. The question is as to the limits which Parliament must have intended, as ascertained by accepted principles of statutory interpretation.

[256] To apply a literal meaning to the words would create an absurdity. It would include effects known and unknown. In an area of rapidly developing technology it can be expected that there may be unknown possible effects and this could be so in respect of any GMO subject to an application even when the constructs are able specifically to be defined.

[257] The intention and purpose of s.40 is to ensure that an applicant who seeks approval from the Authority to import, develop or field test a new organism in containment puts before the Authority all relevant information including importantly, information on all possible adverse effects of the organism on the environment. The clear and all embracing words of s.40(2)(a)(v) (which are repeated in s.40(2)(b)(v) in relation to applications for field testing) clearly place the obligation to provide information about adverse effects on the applicant. The applicant is the party best able to identify what those adverse risks might be and to provide information about them to the Authority. The Authority is entitled to rely on that information but it is not limited by it. It will receive information on adverse effects from a number of sources including its own knowledge and researches, submissions from interested parties, and any further information it may decide to seek pursuant to s.58 of the Act. The Authority then has the responsibility to weigh and balance the information it receives from all quarters and eventually to determine whether the beneficial effects of having the organism in containment outweigh the adverse effects of the organism should the organism escape (s.45(1)(a)(ii))

[258] "Strict grammatical meaning must yield to sufficiently obvious purpose" (*McKenzie v Attorney-General* [1992] 2 NZLR 14, 17 (CA) per Cooke P). The yielding which the Authority adopted in respect of this application was necessary to avoid an absurdity, and consistent with the obvious purpose of s.40 in the context of the Act, to ensure that from the applicant the Authority receives adequate and proper information as to all possible adverse effects to enable it validly to consider the application and to carry out its responsibility to weigh the possible adverse effects in terms of their risk profiles.

[259] It is relevant also that under s.62(2)(a) the Authority has the power to reassess any new organism in containment on the request of "any person or the Chief

Executive of the Authority" where "significant new information relating to the effects of the organism has become available".

[260] This provision recognises that in an area of rapidly developing science, information about potentially adverse effects may come to light subsequent to the determination of an application by the Authority. Such a provision would not be necessary if it were always practical or possible for an applicant to comply strictly with its obligations under s.40 at the time of application. But the reality of the situation is that compliance in strict terms with the s.40 requirement of the applicant to identify and inform as to all the possible adverse effects of the organism, may well be impractical or impossible or both.

[261] The Authority's approach to this aspect, after taking legal advice and considering the implications, was to import a standard of reasonableness in determining whether in this case, there was sufficient information supplied to meet the requirement of s.40(2)(a)(v). As with so many aspects of the processes under the HSNO Act, assessment of the nature, quality and extent of the information provided by the applicant under s.40(2)(a)(v) requires the application of expert judgment. It would be inconsistent with the purpose, intent and structure of the Act to suggest that if in the course of pursuing the processes and procedures under the Act (to receive an application, inquire into it, notify it to the Minister and publicly notify it, hold a public hearing and receive submissions and seek further information where that was considered appropriate), an adverse effect was identified which had not been covered by the applicant, that the application should be immediately dismissed because of non-compliance with s.40. Rather, that adverse effect would be factored into the Authority's considerations in balancing risks and benefits. The process under the Act is directed to ensuring that adverse effects and potential adverse effects are identified, and that those adverse effects are managed and controlled to the extent that in balancing benefits and risks, the Authority can be satisfied that benefits outweigh risks.

[262] Because the Authority is entitled to look to the applicant to provide it with a body of core information from which it can proceed to assess the adverse effects of the organism, the Authority would expect to receive from the applicant, and indeed

the applicant is required to provide under s.40(2)(a)(v), full information about adverse effects and possible adverse effects. But for the Authority to exercise a judgment that a bare level of information had been provided by the applicant and that AgResearch had "possibly" failed to identify all possible adverse effects, did not require the Authority to decline to consider the application.

[263] It is convenient here to revert to the s.7 **Precautionary Approach** to which frequent reference was made in MAdGE's submissions as general support for MAdGE's claims that the approach of the Authority to applications should be strict, and indeed restrictive. It is unnecessary for the purposes of this judgment to attempt a full analysis as to the meaning and ambit of s.7. Suffice to observe that in requiring persons exercising functions, powers and duties under the Act to "take into account the need for caution in *managing* adverse effects", the section recognises that there will, or at least may be, "adverse effects" of the hazardous substances and new organisms with which the Act is concerned. These effects need to be managed where there is scientific and technical uncertainty about them. The section is not directed to the identification, assessment or balancing of adverse effects, all of which are specifically covered by Part V of the Act. Nor is it directed to the prevention of adverse effects. It is concerned with exercising caution in managing identified known or possible adverse effects in situations of scientific and technical uncertainty.

Conclusion on the fourth cause of action

[264] Accordingly I conclude that the decision of the Authority to approve the AgResearch application is neither unlawful or of no effect.

Result

[265] The application is declined. The prayers for relief sought by the applicant are refused.

Costs

[266] Counsel for the respondents may file memoranda as to costs within 28 days. The applicants may file in response within a further 7 days.

[267] However, I note from the judgment of France J of 15 April 2003 in relation to security for costs that there was an acknowledgement by MAdGE that the threshold test of inability to pay had been met. In that circumstance, issues of costs will benefit from discussion by counsel. If memoranda are submitted to me in accordance with the above timetable they should refer to such discussions and the outcome of them.

Concluding observations

[268] In its submissions MAdGE referred to the constraints of lack of resources on its ability to obtain relevant expert evidence and to debate with the proponents of genetic modification. It contrasted that situation with the position of significant players such as AgResearch, in the bio-technology industry. It stated –

> In this context, independent, rigorous and transparent risk assessment and management is vital in the building of trust between the bio-technology community and the wider public.

[269] I concur as to the need for independent, rigorous and transparent risk assessment and management by the Authority and those on whom powers and responsibilities are conferred under the HSNO Act. Parliament has vested powers, functions and responsibilities in the Authority expressly for carrying out the purposes of the HSNO Act. The responsibilities carried by the Authority and ERMA New Zealand which supports the Authority with advice and expertise, are onerous. In exercising her power to appoint members of the Authority under s.15, the Minister must ensure that the Authority has the necessary expertise to perform its functions and "a balanced mix of knowledge and expertise" in matters likely to come before it.

[270] The Authority has the obligation and responsibility to receive, investigate, consider and determine applications under the Act. That will inevitably involve the

Authority in making some decisions which do not accord with the views of opponents to genetic engineering. But when such decisions are made by the expert body appointed for the purpose, in accordance with the requirements of the Act and the orders and regulations made under it, the Court will not intervene to reassess the merits of the scientific judgments made. That is not the role of the Court either on appeal or judicial review.

Judith Potter, J.

Delivered at 9.30 am/~~pm~~ on 7 July, 2003.

SCHEDULE

Section 2(1) : Definitions

"Containment" means restricting an organism or substance to a secure location or facility to prevent escape; and includes, in respect of genetically modified organisms, field testing and large scale fermentation:

"Containment facility" means, -

(a) In relation to new organisms (other than genetically modified organisms), a facility registered as a containment facility under the Biosecurity Act 1993:

(b) In relation to genetically modified organisms, a facility which complies with the controls imposed by an approval granted under section 42 or 45 of this Act:

"Containment structure" means a containment facility that is a vehicle, room, building, or other structure, set aside and equipped for the development of genetically modified organisms.

"Develop", in relation to organisms, means genetic modification of any organism; but does not include field testing.

"Effect" includes -

(a) Any potential or probable effect; and
(b) Any positive or adverse effect; and
(c) Any temporary or permanent effect; and
(d) Any past, present, or future effects; and
(e) Any acute or chronic effect; and
(f) Any cumulative effect which arises over time or in combination with other effects:

"Environment" includes -

(a) Ecosystems and their constituent parts, including people and communities; and
(b) All natural and physical resources; and
(c) Amenity values; and
(d) The social, economic, aesthetic, and cultural conditions which affect the matters stated in paragraphs (a) to (c) of this definition or which are affected by those matters.

"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

trials; and includes large-scale fermentation of micro-organisms.

"Genetic element", in relation to a new organism, means -

(a) heritable material; and

(b) any genes, nucleic acids, or other molecules from the organism that can, without human intervention, replicate in a biological system and transfer a character or trait to another organism or to subsequent generations of the organism.

"Heritable material", in relation to a new organism, means viable biological material, including gametes and spores, arising from the organism that can, without human intervention, regenerate the organism or reproduce a new generation of the same species of the organism.

"Identification" means the provision of any information about a substance or organism which -

(a) Clearly identifies the chemical or biological nature of the substance or organism.

(b) Specifies the nature and degree or type of hazard intrinsic to the substance or organism.

(c) Describes precautions to be taken by persons managing hazardous substances to avoid injury to people or environmental damage.

(d) Directly or indirectly aids in managing any hazardous effect of a hazardous substance.

(e) Identifies and specifies the means of contacting any person knowledgeable in the management of the substance.

"Organism" -

(a) Does not include a human being or a genetic structure derived from a human being.

(b) Includes a micro-organism.

(c) Includes a genetic structure, other than a genetic structure derived from a human being, that is capable of replicating itself, whether that structure comprises all or only part of an entity, and whether it comprises all or only part of the total genetic structure of an entity.

(d) Includes an entity (other than a human being) declared to be an organism for the purposes of the Biosecurity Act 1993.

(e) Includes a reproductive cell or developmental stage of an organism.

"Release", in relation to new organisms, means to allow the organism to move within New Zealand free of any restrictions other than those imposed in accordance with the Biosecurity Act 1993 or the Conservation Act 1987.

s.2A **Meaning of New Organism**

(1) A new organism is –

...

(d) a genetically modified organism.

(2) An organism ceases to be a new organism when an approval has been given in accordance with this Act for the importation for release or release from containment of an organism of the same kind as the organism

s.4 **Purpose of Act**

The purpose of this Act 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.

s5. **Principles relevant to purpose of Act**

All persons exercising functions, powers, and duties under this Act shall, to achieve the purpose of this Act, recognise and provide for the following principles:

(a) The safeguarding of the life-supporting capacity of air, water, soil, and ecosystems:
(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.

s. 7 **Precautionary approach**

All persons exercising functions, powers, and duties under this Act, including but not limited to, functions, powers, and duties under sections [28A,] 29, 32, 38, 45, and 48 of this Act, shall take into account the need for caution in managing adverse effects where there is scientific and technical uncertainty about those effects

s. 39 **Importation or development of new organisms in containment**

(1) The Authority may approve the importation, development, or field testing of any new organism into containment for the following purposes:
  (a) The development of any genetically modified organism:
  (b) Field testing any new organism
  (c) ...

s. 40. **Application for containment approval for new organisms**
(1) Every person intending—
  (a) To import into containment any new organism; or
  (b) To develop any new organism in containment; or
  (c) To field test any new organism in containment—

shall, before importing or developing or testing, apply to the Authority for approval to import or develop that new organism.

(2) Every application shall be in [an approved form] and shall include any information prescribed, information on all occasions where the organism has been considered by the government of any prescribed state or country, or by any prescribed organisation, and the results of such consideration, information about the containment system for the organism, and, -

(a) For the development of a genetically modified organism, -

(i) The identification of the organism; and

(ii) The description of the project and the experimental procedures to be used; and

(iii) The details of the biological material to be used; and

(iv) The expression of foreign nucleic acid material; and

(v) All the possible adverse effects of the organism on the environment:

(b) For field testing and large scale fermentation of a genetically modified organism,—

(i) The identification of the organism; and

(ii) The purposes of the field testing and large scale fermentation; and

(iii) The genetic modifications of the organism to be tested; and

(iv) The nature and method of field trials and the experimental procedures to be used; and

(v) All the possible adverse effects of the organism on the environment.

(3) The Authority may, by written notice given to the applicant, require the applicant to verify an application by statutory declaration.

(4) An applicant may, by written notice to the Authority, withdraw the application at any time.

s.42 **Rapid assessment of adverse effects for development of genetically modified organisms**

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

(2) If the Authority is satisfied that any development meets the criteria for a low-risk genetic modification specified in regulations made under section 41 of this Act, the Authority may approve the application and impose such controls providing for each of the matters specified in the Schedule 3 to this Act as the Authority thinks fit.

s.44A **Additional matters to be considered for certain developments and field tests**

(1) This section applies to an application—
  (a) to develop a new organism in containment that is a genetically modified organism, to the extent that the development does not take place in a containment structure:
  (b) to field test a new organism in containment if the new organism is a genetically modified organism.

(2) In deciding whether to approve or decline an application, the Authority must 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; and
  (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.

(3) The matters referred to in subsection (2) are in addition to the matters referred to in sections 44 and 45.

(4) In this section, field test does not include large-scale fermentation of micro-organisms inside a containment structure.

s. 45. **Determination of application**

(1) After considering any application for approval made under section 40 of this Act, the Authority (if the application is not approved under section 42 of this Act) may, in its discretion,—
  (a) Approve the application if—
    (i) The application is for one of the purposes specified in section 39(1) of this Act; and
    (ii) After taking into account all the effects of the organism and any inseparable organism, including, but not limited to, the effects on the matters in section 43 of this Act (for applications made under section 40(1)(b) of this Act) or the matters in section 44 of this Act (for applications made under section 40(1)(a) or (c) of this Act), the beneficial effects of having the organism in containment outweigh the adverse effects of the organism and any inseparable organism should the organism escape; and
    (iii) The Authority is satisfied that the organism can be adequately contained; or
  (b) Decline the application in any other case.

(2) An approval under this section—
   (a) must include controls that provide for each of the applicable matters specified in the Schedule 3; and
   (b) may include controls that provide for any other matters in order to give effect to the purpose of this Act.

(3) The Authority shall give its decision in writing, including reasons for the decision, give written notice of the decision to the applicant and every person who made a submission, and publicly notify the decision.

s. 45A. **Controls required for certain developments and for all field tests**

(1) This section applies to an approval under section 45—
   (a) to develop a new organism in containment that is a genetically modified organism, to the extent that the development does not take place in a containment structure; or
   (b) to field test a new organism in containment if the new organism is a genetically modified organism.

(2) An approval—
   (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 destroyed; 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.

(3) In subsection (2), destroyed includes leaving genetic elements to break down or become inactive at the site of the development or field test.

s. 68. **Minister's power to call in applications with significant effects**

(1) Where the Minister considers that the decision on any application under this Act will have -
   (a) Significant economic effects; or
   (b) Significant environmental effects; or
   (c) Significant international effects; or
   (d) Significant health effects; or
   (e) Significant effects in an area in which the Authority lacks sufficient knowledge or experience,—

   the Minister may direct that the Minister will decide the application.

(2) The direction shall include the Minister's reasons for giving it.

(3) ...