IN THE HIGH COURT OF NEW ZEALAND
WELLINGTON REGISTRY

CIV-2010-485-000823

UNDER	Hazardous Substances and New Organisms Act 1996
BETWEEN	GE FREE NZ IN FOOD AND ENVIRONMENT INCORPORATED Appellant
AND	ENVIRONMENTAL RISK MANAGEMENT AUTHORITY First Respondent
AND	AGRESEARCH LIMITED Second Respondent
AND	ELSA NOELINE GANNAWAY A Submitter with a right to appear and be heard

Hearing: 24 November 2010

Counsel: T H Bennion for Appellant
P J Radich and J Bowe for First Respondent
T P Robinson and E Body for Second Respondent
Ms E N Gannaway (a submitter in person)

Judgment: 16 December 2010

In accordance with r 11.5 I direct the Registrar to endorse this judgment with the delivery time of 10.00 am on the 16th day of December 2010.

RESERVED JUDGMENT OF GENDALL J

Introduction

[1] Genetic Modification or Engineering has been, and remains, a topic that attracts controversy. There are competing, strongly held views, as to its desirability and safety, as a concept. But Parliament has legislated for procedures and controls in that area by the enactment of the Hazardous Substance and New Organisms Act 1996, which brought together regulation of hazardous substances and genetically modified organisms.

[2] This appeal is by a society which generally opposes Genetic Engineering, against a decision of the Statutory Authority, ERMA, allowing an application, and imposing controls, upon a research company, to enable it to develop (in containment), genetically modified organisms. The application's purpose is said to be summarised as being to produce human therapeutic proteins, or with altered levels of endogenous[1] proteins for the study of gene function, milk composition and disease resistance.

[3] An appeal to the High Court from decisions of that Authority is available only on a question of law.[2]

Glossary

"*GE FREE NZ*"	–	GE Free NZ in Food and Environment Incorporated (the appellant)
"*ERMA*"	–	Environmental Risk Management Authority (the first respondent)
"*AgResearch*"	–	Agresearch Ltd (the second respondent)
"*HSNO Act*"	–	the Hazardous Substances and New Organism Act 1996
"*GMO*"	–	Genetically Modified Organism

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1 "endogenous" meaning genes and proteins naturally found in the host organism.

2 Hazardous Substance and New Organisms Act 1996, s 126.

Background

[4] The application by AgResearch related to the development (in containment) of a range of new organisms, including genetically modified organisms. The application itself did not list any specific proteins or genes that would be investigated, but provided a very large list of types of generic proteins and genes. ERMA may refuse to consider and grant an application under s 40 if it is not satisfied that its scope was such that it could be adequately considered under s 45 of the Act.[3] This power of ERMA therefore requires that an application be for a proper purpose and the beneficial effects of having organisms in containment must outweigh the adverse effects of the organisms. GE Free NZ, and a large number of other submitters, opposed the application. The documentary and factual material encompasses a very extensive voluminous amount of material.

[5] The Court is not concerned with the merits of the decision or the factual matters or the arguments for and against the application. But in summary ERMA was alive to it having to be satisfied that the scope of the application was such that it could be adequately considered under s 45. ERMA concluded at [4.13] that s 45 provided for the imposition of controls to define and limit the scope of the organisms to be considered prior to assessment of the application, and that the generic nature of the application thus did not prevent ERMA from considering it. Having narrowed the application through controls, ERMA said it was satisfied that the organisms were sufficiently defined to permit assessment of whether they met the threshold for approval. It noted (in [4.1.5] of its decision) that the generic nature of the application did not prevent its consideration, even though the breadth of the description of the range of organisms was a matter for consideration.

[6] ERMA came to the view that the organisms could be adequately contained and that medium beneficial effects outweighed the negligible adverse effects of the organisms. There had been previous consultative steps undertaken with Māori generally, when considering another application, and ERMA did not consider it necessary to consult further at that level in respect of this application, although it

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3 *GE Free NZ in Food and the Environment Inc v AgResearch* [2010] NZSC 71 at [3] as clarified by the Court's Minute dated 7 July 2010 issued in response to an application seeking recall.

imposed a control requiring the establishment of an iwi monitoring group to provide sufficient opportunity for continued ongoing consultation. It did, however, receive submissions from local iwi and hapū, both in favour of, and in opposition to, the application. In summary, ERMA was satisfied that the threshold for approval was met. Accordingly, ERMA exercised its discretion to approve the application.

[7] There is a right of appeal from that decision pursuant to s 126 of the Act. Under s 128 of the Act any person who made submissions to ERMA, and who wishes to be heard on an appeal, may give notice of intention to appear. Ms E N Gannaway has done so and was present. She filed written submissions but did not seek to be heard orally.

[8] The original points on appeal have been refined by agreement between the parties. In a memorandum dated 27 August 2010 they are identified as being:

(a) Did ERMA have no power to deal with the application because it was not a valid application in terms of s 40 because it lacked certain particulars, i.e.

> "(i) identification of the organisms;
>
> (ii) the description of the project and the experimental procedures to be used to create the organisms;
>
> (iii) the details of the biological material to be used;
>
> (iv) the expression of the foreign nucleic acid material;
>
> (v) identification of all of the possible adverse effects of the (alleged undefined) organisms."

(b) Did ERMA err in imposing controls under s 45(2)(b) to limit the scope of the application before assessing it under ss 44A and 45?

(c) Did ERMA err in law in accepting that AgResearch was not required to consult specifically regarding the application beyond local hapū and iwi with links to the land the subject of the application to develop organisms in containment?

[9] It is common ground that the application sought approval to engage in research in respect of a wide range of new organisms. The application was publicly notified on 6 November 2009. Over 1,500 submissions were received, many being co-ordinated (akin to an "electronic petition") which contended that the application was too vague or lacked sufficient information as to the modifications being undertaken for a meaningful submission to be made. After a hearing on 1 and 2 March 2010 ERMA released a decision approving the application, with conditions, on 13 April 2010.

An overview of the legislation

[10] The intention of the legislation is clear. It relates to managing the risks to human health, the community and wider environment of hazardous substances and new organisms. Section 4 defines its purposes as:

> 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.

[11] Those who exercise functions, powers and duties pursuant to the Act are required to adopt a precautionary approach. Section 7 focuses on risk management and says that those persons "shall take into account the need for caution in managing adverse effects where there is scientific and technical uncertainty about those effects." Determining the nature of effects and their management is a factual matter requiring judgments on the basis of technical information and expertise. So, ERMA as an expert body, has been entrusted to decide a particular application on the facts and merits. That is why there is, properly, no appeal on a question of fact but only on issues on error of law. The then Minister of Environment, the Hon Simon Upton, when moving the Bill (as reported from the Select Committee) for its second reading is recorded as saying that:[4]

> much of the judgment to be exercised by the Environmental Risk Management Authority will be predetermined by regulation. 'The regulations are developed through a public consultation process, and all interested parties can make their views known. [ERMA] will then assess a substance or organism and, in light of the regulations make a decision. So the likelihood of [ERMA] making a mistake in terms of the facts of a

[4] (16 April 1996) 554 NZPD 11899.

> particular approval is very remote. It is more likely that any mistake will be the result of inadequate or inaccurate information being provided by the application. [Section 62(2)(a)] provides for reassessment on the basis of new information. This will enable such mistakes to be corrected.

[12] The Chairman of the Select Committee is recorded as commenting:[5]

> ... The Environmental Risk Management Authority is required to apply some rigour to the process .... We want an Authority that will base its decisions on rigour and science.

[13] Simon Upton later commented, when moving the Bill for its third reading:[6]

> How risk averse we are as a community is a social, political, and cultural judgment. Technical experts-the sorts of people whom we will be appointing to the Environmental Risk Management Authority-have no special wisdom when it comes to these social, political, and cultural judgments. It is in respect of this matter that the duly elected representatives of the people should have a say and, indeed, the public at large should have a say. I believe that this methodology will be critically important. I am quite sure that it will change over time. The way in which any methodology is applied will have a powerful influence on the weighting to be attributed to any of the matters spelt out in [sections 5 and 6], and the overriding issue of risk aversion that lies at the heart of this legislation.
>
> I have made those comments clear, on the face of *Hansard*, because I think it is going to be important, should the Bill come to be judicially considered, that Parliament's intention is clear. Parliament has chosen clear purpose and principle clauses. It has given clear guidance through the precautionary approach, but it is expecting the actual weightings and the actual level of risk aversion to be governed by a methodology that will be subject to public process.

[14] ERMA has produced application forms, user guides, and directions for applicants to provide guidance as to the information required to be provided in an application. The methodology to be used by ERMA in making decisions on applications is established under the Hazardous Substances and New Organisms (Methodology) Order 1998.

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5 At 11907.

6 (23 May 1996) 555 NZPD 12691.

Section 40

[15] This is central to the challenge by GE Free NZ. It provides, where relevant:

> **40 Application for containment approval for new organisms**
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> (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 [ERMA] 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 an 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 of a genetically modified organism,–
>
> ...
>
> (3) [ERMA] may, ... require the applicant to verify an application by statutory declaration.
>
> (4) An applicant may, ... withdraw the application at any time.

[16] In *GE Free NZ in Food and Environment Inc v Environmental Risk Management Authority and AgResearch* Clifford J summarised what was required

before ERMA could consider and grant applications under s 40 to import, develop and field test genetically modified organisms,[7] which I respectfully adopt:

> a) the identification of the organisms to be imported, developed or field tested (s 40(2));
>
> b) the identification of the procedures whereby imported organisms are to be genetically modified, and the description of the source genetic material to be used for that purpose (s 40(2)(a));
>
> c) the proposed containment system, the nature and purpose of the field tests involved (s 40(2)(b)) and information to enable ERMA to assess and specify the necessary controls; and
>
> d) all the possible beneficial effects of having the organism in containment and all of the adverse effects of the organism on the environment.
>
> Identification of the organism will include information from prescribed states and countries' consideration of the organism (s 40(2)). That and adverse effects under (d) are what will enable ERMA to assess the effects of the organism if it were to escape (ss 40(2)(a)(v) and (b)(v); 44A(2); 45(4)) – including its ability to establish a self-sustaining population and the ease of eradicating such (ss 37; 45(1)(a)(ii)). Identification of the organism, the containment systems, the nature of the field tests and information as to the necessary controls will enable ERMA to assess the probability that the organism will escape (ss 44(b); 45(4)). The nature and purpose of the field and containment system, the controls and the assessed adverse effects will allow ERMA to consider whether there is an alternative method of achieving the purpose with fewer adverse effects (s 44A(2)(b)).
>
> Together, this information is designed to enable ERMA to assess whether the benefits of having the organism in containment outweigh the adverse effects of the organism and any inseparable organism (s 45(1)(a)(ii)), and to be satisfied as to whether the organism can be adequately contained (s 45(1)(a)(iii)).

[17] When determining an application ERMA is governed by s 45. It provides, where relevant:

> **45 Determination of Application**
>
> (1) After considering any application for approval made under section 40 of this Act, [ERMA] ... may, in its discretion,—
>
> (a) Approve the application if—

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[7] *GE Free NZ in Food and Environment Incorporated v Environmental Risk Management Authority and AgResearch Ltd* HC Wellington CIV 2008-485-2370, 5 June 2009 at [48] – [50].

(i) The application is for one of the purposes specified in section 39(1) of this Act;[8] 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; and

(iii) [ERMA] 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;[9] and

(b) may include controls that provide for any other matters in order to give effect to the purpose of this Act.

(3) [ERMA] 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.

(4) In taking into account the adverse effects of the organism ... [ERMA] must take into account—

(a) the adverse effects (if any) of having the organism and any inseparable organism in containment; and

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

(c) the effects of the organism, if the organism were to escape.

[18] Section 44A provides:

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;

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8 These include importation, development or field testing of any new organism into containment for the purposes of the development of any new organism and other purposes unrelated to this application.

9 Schedule 3 outlines matters to be addressed by containment controls for importing, developing or field testing genetically modified organisms, new organisms and hazardous substances.

(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, [ERMA] 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 few 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.

...

The submission of Ms E N Gannaway

[19] This was received in writing and, to a large extent, contained factual submissions not falling within the agreed points of law. But, in essence, she submitted:

> ERMA's granting, with controls, of AgResearch's application (ERMA 200223) appears to be in error as the application failed to meet requirements under Section 40 of the Hazardous Substances and New Organisms Act (1996) and its Methadology Order (1998).
>
> For the development of a GM organism, Section 40 requires that the organism be identified, and that details be supplied of the biological material to be used and the expression of foreign nucleic acid material. All possible adverse effects of the organism on the environment should be considered. In this regard, the application was deficient.

[20] Her submission dealt with her concerns for animals, the environment and health issues, referring to unpredictable outcomes of transgenic experiments, economic and ethical objections. These considerations, whilst matters of general debate, are outside what the Court is able to consider when dealing with precise points of law.

[21] I now turn to consider each of the three agreed points on appeal in turn.

Generic application

[22] This is the point on appeal (a) that the application was not sufficiently particularised to afford ERMA jurisdiction to consider it.

Appellant's submissions

[23] The appellant's primary ground is that the application is ultra vires the Act because it does not comply with the requirements for an application under s 40. The appellant does not contest that generic applications may be made but argues that Parliament intended that certain information is required under s 40, to enable adequate risk assessment to be undertaken as well as meaningful public engagement on the issue of risk. In essence it contended that the breadth of the application, description of genetic materials that may be used and the related purpose means the proposals or investigations of AgResearch may be pursued without limit. It says that in permitting an application as so framed, ERMA effectively delegated aspects of its "decision making to AgResearch ... to determine what diseases and classes of diseases it wishes to research, and what particular treatments it will seek to deliver with milk proteins".

[24] I distil the appellant's propositions into seven bases.

[25] First, that the Act is risk averse. Indeed, the appellant suggests that the Act is "a no risk statute". In that light, the appellant contends that the Act requires a proposed GMO by GMO approach to applications, not an application which allows broad brush research. Accordingly the Act requires detailed information about proposed genetically modified organisms.

[26] Second, that there is a particular regime for GMO under the Act that recognises the special precaution required in dealing with them and the stages of their progress from a modified cell in a lab to a full grown plant or animal in the field. The appellant argues that this is evinced by the legislative history of the Act,

in particular the late amendments to what is now s 40. Following the Select Committee stage, the information requirements in s 40 were changed. The explanatory note to that Supplementary Order Paper provides:

> The proposed amendments to *clauses 26 and 33* clarify the requirements to provide information for the development, field testing, and large scale fermentation of a genetically modified organism.

[27] The provisions were therefore enlarged to provide more extensive requirements to describe the host organism, project, experimental procedures, details of the biological material and expression of the foreign DNA were imposed. Section 40 now provides (see [15]) specific defined information to be supplied so as to enable reasonable and proper assessment of risks to be made.

[28] Third, that an application must specify the organism to a "reasonable certainty" as s 20 provides that a public register of all applications shall be kept by ERMA that specifies, in accordance with s 20(2):

> (a) The name and address of the applicant:
>
> (b) A sufficient description of the substance or organism to uniquely identify that substance or organism:
>
> (c) The purpose of the application:
>
> (ca) if applicable, the project concerned:
>
> (d) Whether the application was approved or declined:
>
> (e) Any controls attached to the approval by [ERMA], including any associated permissions granted under section 95A and any associated licences granted under section 95B:
>
> (f) All the controls on a hazardous substance, whether the controls are imposed under this Act or any other Act.

This, it says, was not done.

[29] Fourth, the detailed forms and user guides, as well as the annotated commentary to the Methodology Order issued by ERMA while non-statutory, represent ERMA's interpretation of the Act and support a precise definition with regard to GMOs. The appellant argues that those forms and user guides contemplate

the provision of a greater level of specificity than is provided here. The appellant provides the following example:[10]

> Generic descriptions
>
> While a complete taxonomic description of each organism is usually required, ERMA New Zealand may be able to accept a broader approach if a complete taxonomic description is difficult or problematic, within the latitude provided by the requirements of the HSNO Act. Broader applications may be used where the host organism(s) are clearly identified, but the range of modifications is broad.
>
> The bounds of a generic description need to be clearly defined so that it can easily be determined what is and is not able to be included in the description, and the risks from the different modifications are similar...
>
> Generic applications that do not specifically identify the host organisms are not acceptable. For example, "genetic modification of Bacillus species with pBluescript containing Bacillus species genes" is not acceptable because the host species are not fully identified, and the risks for different Bacillus species vary. A generic application should reflect the scope of the work you intend to do in the near future and is not intended to provide a carte blanche for open-ended research.

[30] Fifth, the approach taken by Potter J in *Mothers Against Generic Engineering Inc v Minister for Environment (MAdGE)* does not apply in this case because that dealt with a different and distinguishable application.[11] That approach was:[12]

> Given that nothing in the Act expressly prohibits or prevents an application for more than one organism, i.e. a generic application, nor prevents [ERMA] from granting approval for more than one organism, i.e. generic approval; and given that whether or not there has been compliance with the Act's requirements will invariably depend on expert assessment as to whether there has been "identification" in terms of s 2 and the provision of information sufficient to meet the description and details required by s 40(2)(a) in relation to a development, there is no basis on which the Court could or should intervene to substitute its assessment of the application for that made by [ERMA] as to whether the application fulfilled the statutory requirements for it to be *considered* by [ERMA]. That [ERMA] preferred its assessment of the information to the view taken by other experts including those for MadGE, does not constitute a jurisdictional error which is reviewable by the Court.

[31] Sixth, that by considering such a broad application negated submitters' ability to engage and provide constructive submissions on the application. Such an

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10 ER-UG-NO30-1 -5/04 at 9.

11 *Mothers Against Generic Engineering Inc v Minister for Environment (MAdGE)* HC Auckland CIV 2003-404-673, 7 July 2003.

12 At [204].

approach is contrary to the intention of the Act which provides for the consideration of societal values to be balanced and not left entirely to expert assessment.

[32] Seventh, that by considering such a broad application, ERMA could never have properly undertaken the analysis required of it under ss 44A and 45 of the Act, in particular, in assessing the risks involved with the application. As such, it has effectively delegated an aspect of its decision making to ERMA.

Arguments of AgResearch

[33] AgResearch structured its submissions as a response to each of the points made by the appellant.

[34] In response to the first, AgResearch argues that s 45 requires a broad enquiry and ERMA is not, on the face of the Act, directed as to how this enquiry should be conducted. In particular, it is not directed to assess genetic modification applications on an organism by organism basis, as contended by the appellant. The Methodology Order does provide some guidance, but it does not require an organism specific analysis.

[35] In response to the second, while AgResearch accepts that the Act recognises that GMOs raise discrete issues that need to be addressed in the approval process, the Act does not require ERMA to take special precautions in dealing with genetic modification applications as compared with any other hazardous substance. A more nuanced approach than that contended for by the appellant is required. For example, s 44A requires ERMA to consider alternative methods of achieving the same result when considering an application concerning GMOs. Within that provision a distinction is drawn between development applications within a containment structure, to which s 44A does not apply, and those in containment but outside the laboratory. With respect to the amendment contained in the 21 May 1996 Supplementary Order Paper, AgResearch contends that the appellant cannot point to any direct explanation for this change; the cautious approach adopted in the Bill, as reiterated in the debates recorded in Hansard, needs to be read in context. Those

discussions focussed on an explanation of the precautionary approach. They add nothing to an interpretation of s 40.

[36] In response to the third, AgResearch relies on the discussion of the Supreme Court in *Wyeth (NZ) Ltd v Ancare New Zealand Ltd*.[13] In summary, AgResearch contends that to argue that s 20 assists the interpretation of s 40(2) is to put the horse before the cart.

[37] In response to the fourth, AgResearch says that the commentary to the Methodology Order must be read in light of the terms of the Order itself, as required under s 5(b) of the Act. In that light, the use of a gene library set out in AgResearch's application is provided for in the user guides published by ERMA. Nevertheless, AgResearch contends that the appellant has not identified any aspect of the Methodology Order that ERMA did not comply with and that ERMA undertook the same approach to the application in this case as it did in relation to the application at issue in the *MAdGE* decision.

[38] In response to the fifth, AgResearch argues that the purpose expressed in its present application is analogous to that in *MAdGE*. The application is also much narrower than the application considered by Clifford J. Further, AgResearch contends that the application considered in *MAdGE* also described a host organism and a wide range of potential modifications and exclusions such as that considered here.

[39] In response to the sixth, AgResearch submits that the appellant still could have tested the assumptions on which the application was based. However, the appellant chose not to do that, and rather stated that it was unable to comment.

[40] In response to the seventh, AgResearch submits that ERMA has used appropriate exclusions to ensure identified adverse effects were avoided, and therefore could, and did, undertake the analysis required of it. Further, AgResearch says that the important thing is not that a particular decision leaves some discretion open to the approval holder, but rather that the decision ensures that the scope of any

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[13] *Wyeth (NZ) Ltd v Ancare New Zealand Ltd* [2010] NZSC 46, [2010] 3 NZLR 569 at [50] – [51].

such discretion is appropriately limited so that there is no realistic risk of effects occurring which have not been considered and determined to be acceptable by ERMA.

Arguments of ERMA

[41] These spanned many pages but essentially came down to contending that:

- The application contained appropriate and sufficient information to afford ERMA jurisdiction to deal with it. ERMA identified host organisms, and an extensive library of genetic material that might be used in the proposed research. In that light, ERMA contended that a finding that insufficient information was not provided is a factual finding, and should only be set aside if there was no evidence to support it.

- A table was tendered to illustrate what information was required, and where in the application it is located. Those are matters of evidence but relevant, it was said, to answer the criticism of the appellant. The table in part reads:

Information requirement	**Location of information in the Application**
Identification of the genetically modified organisms, s 40(2)(a)(i)	Pages 11 – 14; 15 – 19; 26 (exclusion of viruses); Pages 8, 32 – 50 describe the organisms' possible hazards; See also Appendix II pages 1 – 517 list the non-pathogenic E.coli; pages 673 – 728 list the mammalian cell lines, pages 517 – 518 list the protein types that will be expressed in the host organisms.

Description of the project and the experimental procedures to be used, s 40(2)(a)(ii)	Pages 6, 9, 14 and 18 describe the project. Page 20 sets out the experimental procedures to be used.
Details of the biological material to be used, s 40(2)(a)(iii)	Appendix II contains a complete list of the biological material to be used.
Expression of foreign nucleic acid material, s 40(2)(a)(iv)	Pages 15 and 18 describe the expression of foreign DNA, page 15, 17: no infectious vital particles will be developed.
Identification of all the possible adverse effects on the environment, s 40(2)(a)(v)	Pages 32 – 42.

[42] ERMA argued that it had followed the Methodology's requirements, involved public participation, and followed a rigorous process with expert and scientific input to decide whether the application met the requirements of the Act, so that subject to controls it might properly be granted.

Discussion

[43] The scheme of the Act is risk averse, as exemplified by s 7. Indeed, that is further illustrated by the many Hansard debates cited by the appellant.[14] However, it cannot be said that it is a "no risk" statute. There is always a risk inherent in the approval of any new research endeavour. Section 6(e) foreshadows that and requires that those risks be considered alongside the economic and related benefits and costs of using a particular hazardous substance or new organism. Further, s 20 cannot be interpreted to assist the appellant. In considering whether material which was

[14] See, for example, Simon Upton (23 May 1996) 555 NZPD 12691.

withheld under s 57 must be disclosed on the register under s 20, the Supreme Court did not consider that:[15]

> Parliament's purpose was to require public disclosure of information additional to what was made available under the provisions of Part 5.

[44] The Court came to that conclusion, in particular as s 20 is a "machinery provision". The Court accepted the submission of its amicus curiae that:

> [the provisions] simply suggest that keeping a public register showing all applications received, and what had happened to them, was seen as a desirable part of the Authority's administrative operations. The register does not provide a comprehensive record of all hazardous substances lawfully present in New Zealand, only those which are the subject of applications made to the Authority.

[45] I consider that reasoning to be equally applicable to the present case. Section 20 cannot require what is not required under Part 5, therefore it cannot be determinative as to whether more particularised information is required. I accept, as did the Court of Appeal in *AgResearch Ltd v GE Free NZ in Food and the Environment Inc* at [18], that as an application must be "in an approved form" brings into play the application forms and associated user guides, but the various forms, user guides and commentary to the Methodology Order cannot be *determinative*. These are merely guidance to submitters, but cannot be said to be binding on ERMA. In any case, the appellant has not pointed this Court to any particular guidance that prohibits an application of the kind submitted in this case. Nor is there anything in the Methodology Order itself which prohibits a "generic" application per se.

[46] Parallels were sought to be drawn by the appellant between this case and that considered by Clifford J. I now turn to discuss the differences in approach.

[47] Section 40(1) requires that an application for approval must be made to ERMA by a person who intends to develop or field test any new organism in containment. Section 40(2) sets out the requirements for any such application (see above at [15]). In *AgResearch Limited v GE Free* the Court of Appeal allowed an appeal against the decision of Clifford J in which his Honour had upheld an

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15 *Wyeth (NZ) Ltd v Ancare New Zealand Ltd* [2010] NZSC 46, [2010] 3 NZLR 569 at [50].

application by GE Free for judicial review.[16] Clifford J found that ERMA had erred in law in receiving four applications by AgResearch under s 40 of the Act and commencing the process of determining those applications.[17] Clifford J found that the applications did not comply, inter alia, with the requirements of s 40(2). The applications were, in essence, too generic with insufficient detail or particulars to enable ERMA to undertake the risk assessment that it is required to undertake under s 45 of the Act.

[48] Clifford J summarised the very broad nature of the applications as allowing, if approved:[18]

> AgResearch first to import into containment specified organism types of the specified livestock, laboratory animals and other organisms, already genetically modified in ways not previously present in New Zealand. Once imported, AgResearch could further genetically modify those organisms whilst in indoor containment. Finally, AgResearch could further genetically modify in outdoor containment, and field test, the specified livestock.
>
> AgResearch could use any technique available, now or in the future, to effect such genetic modification and could do so using genetic material from the specified livestock, small animals, humans and monkeys, *E. coli* and yeast organisms as specified in the Applications. Each of those approvals could be implemented at Ruakura, or at yet to be located facilities.

[49] The Court of Appeal allowed the appeal because the proceedings for judicial review had been brought prematurely (the applications had not been heard). Merely receiving applications was considered to be an "essentially mechanical decision" and therefore that decision was not of sufficient moment to be appropriately the focus of judicial review.[19] The Court of Appeal went on to note:[20]

> The specific matters referred to in s 40(2) are not the only requirements applying to applications under s 40(1). The requirement that the application "include any information prescribed" also brings into play the Hazardous Substances and New Organisms (Methodology) Order 1998, which sets out a methodology to be used by ERMA in making decisions in relation to applications. Similarly, the requirement that the application be "in an approved form" brings into play the application forms and associated user guides which ERMA has itself produced.

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16 *AgResearch Ltd v GE Free NZ in Food and the Environment Inc* [2010] NZCA 89.

17 *GE Free NZ in Food and the Environment Inc v Environmental Risk Management Authority* HC Wellington CIV 2008-485-2370, 5 June 2009.

18 At [60] – [61].

19 At [59].

20 *AgResearch Ltd v G E Free NZ in Food and the Environment Inc* [2010] NZCA 89 at [18].

[50] But the Court of Appeal declined to determine whether the generic nature of the applications in that case meant that they had failed to comply with specific requirements in s 40(2). The Court concluded:[21]

> We accept that there is a real issue as to whether the generic nature of the applications means that they fail to comply with what appear to be relatively specific requirements in s 40(2). However, we also accept the submission made on behalf of both AgResearch and ERMA that the determination of that issue is a matter requiring a degree of scientific knowledge and the application of that knowledge to the case at hand in circumstances where it will not be readily apparent to ERMA at the time it accepts the application, and which will be difficult for a Court to evaluate in judicial review. On the approach we take to the case it is not necessary for us to express a concluded view on this issue, because we see the outcome of the appeal being dependent on our views on the second issue, to which we now turn.

[51] The Court went on to add that:[22]

> We do not discount the importance to organisations such as GE Free, which wishes to take an active role in proceedings before ERMA, of having a clear understanding of the proposal to which they are to respond. But we do not accept [counsel's] proposition that ERMA has a statutory obligation to vet each s 40(1) application and to reject it if it is not satisfied that the application complies strictly with the statutory requirements. That is not to say that ERMA is obliged to accept everything which an applicant claims is a s 40(1) application, regardless of any obvious deficiencies.
>
> Ultimately ERMA has to satisfy itself, prior to making its decision under s 45, that the application before it (as modified or clarified in the course of ERMA's consideration) is an application falling within the scope of s 40 and to which ERMA's approval can be given.

[52] In the decision of *MAdGE Inc v Minister of Environment* Potter J dealt with a similar argument to that advanced here, namely that there was insufficient information in the application to satisfy the legal requirements of ss 40(2)(a) and 20(2)(b). Her Honour concluded:[23]

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

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21 At [35].
22 At [55]-[56].
23 At [200].

and further:[24]

> Given that nothing in the Act expressly prohibits or prevents an application for more than one organism, i.e. a generic application, nor prevents [ERMA] from granting its 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 on which the Court could or should intervene to substitute its assessment of the application for that made by [ERMA] as to whether the application fulfilled the statutory requirements for it to be *considered* by [ERMA]. That [ERMA] preferred its assessment of the information to the view taken by other experts including those for MadGE, does not constitute a jurisdictional error which is reviewable by the Court.

[53] I have, at [49] – [51] set out the obiter remarks of the Court of Appeal which seem to emphasise that determination of what information is necessary may be:[25]

> a matter requiring a degree of scientific knowledge and the application of that knowledge to the case in circumstances where it will not be readily apparent to ERMA at the time it accepts the application, ...

[54] Identification is defined in s 2:

> "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.

[55] I agree with Potter J that this must inevitably encompass expert assessment, and the courts must recognise that Parliament, having established an expert authority to hear and determine these applications, did not envisage a narrow legalistic approach being taken when legal challenges are made. So whilst an individual organism is required to be identified and described, the scope of the description must be such that modification or refinement may be made. As such "special precautions" are not required in the dealing with an application for a GMO under the Act. The

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[24] At [204].
[25] At [35].

Act, as noted above, is generally risk adverse. That much is clear in s 4. But where ERMA considers that it has sufficient information to undertake a proper analysis under ss 45 and 44A that will be sufficient.

[56] Although Clifford J in *GE Free NZ in Food and the Environment Inc v Environmental Risk Management Authority* reached a different conclusion to that of Potter J, the applications which his Honour had to consider were significantly different from those in *MAdGE*, and in the present case.

[57] Clifford J was concerned with a challenge to applications to import into New Zealand and use nine new genetically modified forms of genera, with no restriction on the type of modification that might be involved or limit on the technique applied to modifications. Further the location and stated purposes of the research were expressed inclusively, leaving the potential for subsequent additions. His Honour commented:[26]

> In particular, and as recognised in the *MadGE* decision, the decisions called for under [the Act] are at their heart scientific and expert. They are not decisions with which this Court will readily interfere.

But his Honour concluded that ERMA did not have sufficient information to be able to carry out any risk assessment.

[58] The contention alleged by the appellant is perilously close to the law/fact divide. In this case there was a wealth of particulars provided to enable ERMA to consider the application, which was for research in a contained environment.

[59] I accept the proposition by the appellant that public consultation is an important feature under the Act. Indeed, s 59(4) provides, in light of ERMA's power to waive any information requirement under the Act under s 59(3)(a)(ii):

> (4) The Authority shall not extend or reduce any time period or grant an application under this section to waive a requirement as to the time within which any action shall be carried out unless it is satisfied that—

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[26] At [127].

(a) The applicant and the persons making submissions consent to that waiver; or

…

[60] Thus, there is a minimum required in order to ensure that submitters can constructively engage in the process. There may be some situations where submitters cannot constructively make submissions on an application to ERMA, where an application has been publicly notified either mandatorily or under its discretion under s 53 of the Act, and therefore the application is not sufficient to allow ERMA to consider it. This is not such a case. It would be an unlikely event for ERMA to consider there to be sufficient information for it to conduct a meaningful determination under s 45, yet there was insufficient information for submitters. Also under the Act, submitters are given access to the summary of the application prepared under cl 7 of the Schedule to the Hazardous Substances and New Organisms (Methodology) Order 1998. That summary is not necessarily all of the information that ERMA may use in its determination. Under s 52, ERMA may request the applicant to provide further information if ERMA considers that the applicant is able to provide that information, and under s 58 ERMA may require a report to be furnished. It may be that such information is not released to submitters, so it is possible that submitters may never have all of the information available to ERMA (notwithstanding that some information may be withheld, in certain applications, under ss 55 and 57). If submitters are prejudiced by not having access to material adverse to their interests, they may have a "breach of natural justice" ("unfair play") argument to argue in seeking judicial review. But that is not a point of law advanced in the support of this appeal. Rather the appellant relies upon the proposition that ERMA did not have jurisdiction to proceed because it had insufficient particulars.

[61] In my view, ERMA could, and did, avail itself of its expert scientific knowledge in assessing whether the particulars specified in the application sufficiently identified the substance or organism and those matters necessary for it to proceed to consider the application. There was no error in its assuming jurisdiction to consider and deal with the application.

Imposing controls under s 45(2)(b) before assessing the application

Appellant's submissions

[62] The appellant said that controls cannot be imposed prior to considering the assessment under s 45 because ERMA, like submitters, must assess the application on that application's own merits. It accepts that conditions may be imposed to limit the effects of the application, but not redefine the application before it is assessed. If controls are imposed before the application is assessed, it means that ERMA assesses a proposal that neither the applicant nor submitters have ever seen.

[63] The appellant also contends that in any event, the controls do not limit the application. That is not an issue in the agreed points on appeal. However, that appears to be a question of fact, not one of law, and does not require further discussion.

[64] Counsel did not question the adequacy of the description of the host animals, the location and containment facility in the application. But he argued that the description of genetic materials that may be used in the related purposes were so extraordinarily wide as to seek "biofarming" [sic] for any and all diseases, and "human therapeutics" is not defined. The primary and secondary purposes of the application are said to be that they are very wide with terms and types of sources of genetic material to be used capable of modification. Counsel refers to matters of evidence and submissions, which were essentially factual matters for ERMA. Where issue is taken to the substantive part of ERMA's decision that is of little moment because the Court is confined to determining the questions of law agreed between the parties. Nevertheless, for completeness I record the contended deficiencies of ERMA's decision put forward by the appellant are:

- failure to identify any particular modifications;

- assessment of the possibility of escape from containment in the absence of any modifications being identified;

- assessment of economic, social, cultural effects without identification of particular genetic modifications to be undertaken where the application covers the whole range of human diseases;

- adopting the approach that lack of adverse effects over time from GMOs in other areas means that such an extensive application can be entertained without the information required in s 40 being provided;

- AgResearch failed to provide the information required by the Act;

- assessing risk of health and safety beyond parameters set by Parliament;

- submitters were unable to "engage and make meaningful comments or suggest meaningful controls" on scientific, social, economic and cultural aspects contrary to the intention of the Act.

AgResearch's submissions

[65] AgResearch says that controls may be imposed at any stage, as is the case in the Resource Management Act 1993 context. To that end, AgResearch referred to the Environment Court decision in *Coull v Christchurch City Council*.[27] Further, whilst the appellant claimed that ERMA used controls to constrain the scope of AgResearch's applications, it did not as a matter of fact use controls in the manner contended, so the point raised is academic.

ERMA's submissions

[66] ERMA accepts that there is a limit to the extent to which it can impose controls,[28] but says where those controls do not alter the nature of an application or do not redefine an application, the controls are justified, neither of which is achieved here.

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27 *Coull v Christchurch City Council* EC Christchurch C77/06, 14 June 2006.

28 *Contact Energy Ltd v Electricity Commission* HC Wellington CIV-2005-485-624, 29 August 2006.

Discussion

[67] Section 45(2) is set out in [17] and provides that an approval must

> ... include controls that provide for each of the applicable matters specified in Schedule 3; and
>
> (b) may include controls that provide for any other matters in order to give effect to the purpose of this Act.

[68] It is apparent from cl 12(d) of the Methodology Order that at the subsequent hearing and decision-making stage, controls may be taken into account and the position must be that, as the Court of Appeal observed in *AgResearch Ltd v GE Free*,[29] the determination process is rather more nuanced than merely the accepting of an application, receiving submissions on that application, and proceeding to decide it based upon those submissions. In that decision, the Court of Appeal stated:[30]

> We agree with AgResearch and ERMA that the powers to obtain further information under s 52 and reports under s 58 envisage that the pool of information before ERMA in relation to an application will not necessarily remain static during the consideration process. Just as ERMA will have to respond to information emanating from those opposing its application, so will the opposing parties have to respond to the further information that elicited from ERMA under s 52 or from the writers of reports under s 58.

[69] The imposition of controls, whether at the decision-making stage, or during the process of the application being investigated and progressed, is permissible especially where controls are simply a subset of the original application. I reject the argument that, in the context of this highly scientific topic, ERMA is to be prohibited from placing controls under s 45(2)(b) before it assesses the application. It is able to obtain further information and refine an applicant's application. Based upon that information it ought to be able to, and is entitled to, impose conditions at the outset provided they do not enlarge upon the application and that which has been sought.

[70] Further, I do not accept the argument that the words "an approval under this section may include" suggests the controls must always be concurrent with the approval rather than preceding it. If that was the case it would unreasonably fetter or

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[29] *AgResearch Ltd v G E Free NZ in Food and the Environment Inc* [2010] NZCA 89.
[30] At [57].

restrict the powers that ERMA has to have to scrutinise the true ambit and purpose of the application. In my view, s 45(2) does not place restrictions as to when controls may be imposed and ERMA is entitled to refine an application as the process develops, provided that those who are entitled to be heard on any refined or controlled proposal are aware of it.

[71] In the present case, as has been already mentioned, the controls imposed simply repeated the limits of the proposal so no narrowing was actually undertaken and the agreed point of law is academic and of no avail to the appellant.

Failure of AgResearch to consult beyond local hapū and iwi

Appellant's submissions

[72] The appellant contends that in light of ss 5(b), 6(d) and 8, the applicant had a duty to consult with Māori more broadly than merely with local iwi prior to submitting an application in order for ERMA to have sufficient information relevant to matters specified in ss 5(b), 6(d) and 8 of the Act. In the present case, ERMA recognised that wider than local consultation was required, but it explicitly relied in its decision on the results of consultation for a different application – which was later withdrawn. The appellant argues that consultation over one proposal cannot be supportive of consultation over another.

AgResearch's submissions

[73] AgResearch argues that given there is no specific requirement in the Act requiring an applicant to consult with Māori, and applying by analogy decisions under the Resource Management Act 1993, there is no duty on an applicant to consult with Māori generally. Alternatively, the applicant did consult with the relevant Māori entities, and there is no credible basis for there to be any obligation to consult more broadly.

ERMA's submissions

[74] ERMA also contends that the Act does not contain a provision that imposed an obligation on AgResearch to "consult" with Māori. ERMA further clarified that it, itself, obtains information relevant to ss 5(b), 6(d) and 8 from:

a) written submissions made following public notification of an application (ss 53 and 54);

b) oral submissions made at a hearing of the application (ss 60 and 61);

c) previous applications;

d) any report furnished under s 58;

e) Nga Kaihautu Tikanga Taiao, which is a statutory committee established under Part 4A of the Act;

f) any information provided by applicants.

Discussion

[75] The principles to be recognised and applied in this area are, s 5:

> **5 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 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.

And also s 6, which provides as relevant:

> **6 Matters relevant to purpose of Act**
>
> All persons exercising functions, powers, and duties under this Act shall, to achieve the purpose of this Act, take into account the fllowing matters:
>
> ....
>
> (d) The relationship of Maori and their culture and traditions with their ancestral lands, water, sites, waahi tapu, valued flora and fauna, and other taonga.

[76] I accept that there is no requirement on an applicant to consult and ERMA did not err in law in accepting that position. I respectfully agree with what Blanchard J said in *Quarantine Waste (NZ) Ltd v* Waste *Resources Ltd*:[31]

> ... I would have very real qualms about a second-hand consultation, with a local authority leaving it to an applicant to consult with local Maori interests. The potential for distortion by an applicant of their views is obvious. It should be emphasised that the statutory and Treaty obligation of consultation is that of the consent authority – as the local governmental agency – not that of the applicant.
>
> .... [but] the failure to undertake a direct consultation did not bring about a situation in which [the Authority] omitted to consider or take into account a material and relevant factor. It did give some consideration to the effect on Maori of the granting of ... consent.

[77] Even if the applicant were required to undertake broad consultation, to the extent that the appellant contends that ERMA had insufficient information, that cannot be true in the present case under the legislative scheme as identified above.

[78] To "take into account" will require recognition of, and placing on the scales for consideration, those values. In *Bleakley v Environmental Risk Management Authority* the Court stated:[32]

> There is a deliberate legislative contrast between s 5 "recognise and provide for" and s 6 "take into account". When Parliament intended that actual provision be made for a factor, Parliament said so. One does not "provide for" a factor by considering and then discarding it. In that light, the obligation to "take into account" in s 6 was not intended to be higher than an obligation to consider the factor concerned in the course of making a decision – to weigh it up along with other factors – with the ability to give it,

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31 *Quarantine Waste (NZ) Ltd v Waste Resources Ltd* [1994] NZRMA 529 (HC) at 542.

32 *Bleakley v Environmental Risk Management Authority* [2001] 3 NZLR 213 (HC) at [72].

> considerable, moderate, little, or no weight at all as in the end in all the circumstances seemed appropriate.

[79] When read together those two sections require ERMA to provide for s 5 principles and in assessing the import of such principles, to consider (take into account) Māori cultural traditions and values. So, too, would AgResearch (or anyone) when exercising functions, powers and duties. But there is no *requirement* for an applicant to provide information to ERMA broadly on those principles. Naturally, in order to give effect to those two sections, ERMA must have information from which it can consider those matters. It is clear that that information could, potentially, come from a former consultation with Māori. Particularly in circumstances where the Report stated that any further consultation would not have raised any further issues. After all, consulting is listening to what others have said, considering their responses and then deciding what will be done.[33]

[80] ERMA was alive to the directions contained in ss 6(d) and 8,[34] referring at [6.2.24] to consultation with Māori as a means of giving effect to ss 6(d) and 8. It recorded that it had information and material from previous consultations and nothing would have been achieved by further consultation. I cannot discern that the legislative scheme imposed a duty to consult further where, it said (and this was not challenged) that AgResearch had already consulted on matters relevant to ss 5 and 6. Consultation is about discussion, not resolution. It was open to ERMA to decide that it had sufficient information for its resolution. No further discussion was required in order for it to consider what it was required to do under ss 6 and 8.

Conclusion

[81] For the foregoing reasons none of the three agreed points of appeal succeed. ERMA had jurisdiction to deal with the application; it did not err in law in imposing controls which altered the nature of the application; and it did not err in law in accepting that AgResearch was not required to consult Māori interests beyond hapū and iwi.

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33 *West Coast United Council v Prebble* (1988) 12 NZTPA 399 at 411.

34 "s 8 All persons exercising powers and functions under this Act shall take into account the principles of the Treaty of Waitangi (Te Tiriti o Waitangi)."

[82] The appeal is dismissed.

[83] ERMA and AgResearch are entitled to costs. If the parties are unable to reach agreement as to costs, they may submit memoranda.

J W Gendall J

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