IN THE HIGH COURT
WELLINGTON REGISTRY **CIV-2010– 485-823**

UNDER THE	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

Outline of submissions

Dated 8 November 2010

NEXT EVENT: Hearing
Wednesday and Thursday 24 and 25 November 2010, High Court, Wellington

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MAY IT PLEASE THE COURT

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1. SUMMARY OF ARGUMENT

1.1 The Hazardous Substances and New Organisms Act 1996 ("HSNO") sets out an assessment procedure including information requirements that applications to create and test proposed genetically modified organisms ("GMOs") must fulfil so that The Environmental Risk Management Authority ("the Authority") and potential submitters are aware of the scope of the application and have sufficient information to assess the risks arising.

1.2 The applicant, AgResearch, has made an application to "develop in containment genetically modified goats, sheep and cows to produce human therapeutic proteins, or with altered levels of endogenous proteins for the study of gene function, milk composition and disease resistance."[1]

1.3 The application does not list any specific proteins or genes that will be investigated, but instead provides a large list of types of proteins and genes that might be investigated.

[1] Casebook ("CB") vol I p1063 application summary. Altered levels of endogenous proteins means altered levels within the goat, sheep or cows.

1.4 The Authority has approved the application on the basis that, although the list is extensive, when read in light of the purpose of the application (stated above) and with a number of general exclusions, it can be suitably narrowed to the point where risk can be assessed and approval can be given.

1.5 The appellant says that that is ultra vires the Act, in particular:

(a) The Act requires more detail of modifications to be undertaken and identification of the GMOs to be created than has been provided;

(b) The list of possible modifications is so extensive that public input, a critical component in the Act, has been rendered pointless;[2]

(c) The list of possible modifications is so extensive that risk assessment cannot be undertaken as Parliament intended. In effect, the Authority panel has substituted its level of comfort with the risk of GMOs over the rigorous risk assessment approach required by the Act and intended by Parliament;

(d) Because of these problems, the Authority has effectively delegated its decision making power to the applicant.

(e) The authority has relied on conditions as a means of reducing risk which are irrelevant to or at best have little to do with managing the risk – in particular the reliance on the purpose of the application.

1.6 The applicant and Authority rely on the decision in *Mothers Against Genetic Engineering Inc v Minister for the Environment* ("Madge")[3] which said that generic applications are possible. The appellant does not contest that generic applications may be made but this application is quite different from what was considered in the *Madge* case.

1.7 The appellant readily accepts that there are differing scientific views about whether the application is so broad than one can properly assess the risks. This action is not about that, but rather about the information Parliament intended should be provided and therefore the level of risk assessment that Parliament considered was required when it passed the HSNO Act, as well as meaningful public engagement on the issue of risk.

1.8 The final ground of appeal raised is the reliance on a national consultation on another application to satisfy the requirements of the Act which require engagement with and consideration of effects on Māori in particular.

2. FACTUAL BACKGROUND

2.1 GE Free has been involved in previous litigation over the meaning of provisions in the Act[4] and is in regular contact with the office of the Authority about all aspects of policy as well as particular applications. It is one of the 1545 submitters on these applications.

2.2 AgResearch is a research institution based in Ruakura in Hamilton. The applications are summarised by AgResearch as follows:[5]

> AgResearch seeks approval under this application to develop in containment (indoor and outdoor) goats, sheep and cows genetically modified:
>
> • to produce human therapeutic proteins, and
>
> • to alter levels of gene activities and proteins for the study of gene function, milk composition and disease resistance.

2.3 The Authority formally received the applications on the 5 November 2009.

2.4 The application was publicly notified on the 6 November 2009 on the basis that there was "likely to be "significant public interest" in the

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[3] 7/7/03, Potter J, HC Auckland CIV-2003-404-673.
[4] See below.
[5] CB III p3004 para 2.1.3.

application.[6] The Authority has powers to seek further information from an applicant.[7] None was sought.

2.5 The Act requires that submissions close after 30 workings days[8] and that a hearing is held within 30 working days of the close of submissions.[9] There are limited powers to grant a waiver to these time limits on application, but the applicant must agree.[10] No extensions of time were made.

2.6 When submissions closed on the 18 December 2009, 1545 submissions had been received. The overwhelming majority contained an explicit statement or statements that the applications are too vague or lack sufficient information as to the modifications being undertaken for the submitter to make a meaningful submission.[11]

2.7 A hearing was held on the 1 and 2 March 2010 in Hamilton. A decision approving the application with conditions was issued on the 13 April 2010.[12]

3. RELEVANT PROVISIONS OF THE HSNO ACT

General approach of the Act

3.1 The Act is risk averse. Its purpose 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."[13] There is a presumption that new organisms (including GMOs) have adverse effects that require management. This is in

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[6] CB vol III p3135 para 3.1.1. Section 53(2) provides that "The Authority may, if it considers that there is likely to be significant public interest, publicly notify—… (b) an application under section 40 to import into containment or develop in containment a genetically modified organism, if the application has not been approved under section 42, 42A, or 42B;".
[7] s52.
[8] s59(1)(c).
[9] s59(1)(d).
[10] s59(4).
[11] CB vol IV tab 30 & vol III p3012.
[12] CB Vol III Tab 29 p3131.
[13] s4. Section 2 provides that "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..

contrast with, for example, the Resource Management Act 1991 whose purpose is neutral as to adverse effects, merely requiring them to be managed should they arise.[14]

3.2 Section 7 provides for a "precautionary approach" in the face of scientific and technical uncertainty about adverse effects to be taken when exercising functions, powers, and duties under the Act, including in particular decisions under section 45.[15]

3.3 The adverse effects which the Act is concerned with are not just biological and physical, they are also social, economic and cultural. This is clear from several provisions. Section 2 defines environment as "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) or which are affected by those matters. Section 6 provides:

> 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 following matters:
>
> (a) the sustainability of all native and valued introduced flora and fauna:
>
> (b) the intrinsic value of ecosystems:
>
> (c) public health:
>
> (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:
>
> (e) the economic and related benefits and costs of using a particular hazardous substance or new organism:
>
> f) New Zealand's international obligations."

3.4 Unusually, the Act provides that a Methodology is to be established by Order in Council "which includes an assessment of monetary and non-

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[14] s5(2) RMA 1991.

[15] "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, shall take into account the need for caution in managing adverse effects where there is scientific and technical uncertainty about those effects.".

monetary costs and benefits" for making decisions on the assessment of hazardous substances and new organisms.[16]

3.5 During the passing of the legislation, there was extensive debate about what the overall outcome for approvals should be under the Act. The Bill proposed a test of net national benefit, but there was dispute about what that might mean. Parliament determined that the legislation should not state the overall outcome required, but that a methodology, shaped by stakeholders, including the public, and more easily amended than a statute, should direct the Authority how to approach its assessment of risk. The intention was explained as follows:[17]

> "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 Environment Risk Management Authority - have no special wisdom when it comes to these social, political and cultural value 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 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 clauses 5 and 5A, and the over-riding issue of risk aversion that lies at the heart of this legislation."

3.6 Later he said:[18]

> So, providing for a methodology requires a public forum to debate these issues, and they will change with time. I have no doubt that at some future point the ERMA will make a decision, and people will say: "Was that decision possible under the methodology? Yes, it was. We dont like the decision, That means that the value judgments being applied are ones that are no longer socially relevant. We want to reassess the methodology."

3.7 The Authority has issued an annotated version of the Methodology which explains its provisions. The relevant ones in this case are:[19]

> C. APPLICANTS
>
> In making applications, applicants will be responsible for:
>
> • providing necessary and sufficient information (including a risk assessment for the adverse effects which could follow from the introduction of a hazardous substance or new organism) so as to enable the Authority to make its decisions in accordance with the Act and the Methodology Order.

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[16] Section 9.
[17] Upton 23 May 1996 NZPD (1996) p12691.
[18] Ditto p12685.
[19] p 7, CB vol VI p6284.

> • providing valid applications in the form prescribed, including unequivocal identification of the hazardous substance or new organism that is the subject of the application.
>
> • providing a summary of information, including risk assessments and estimated costs and benefits, for public release which has sufficient detail so that it is clear what the application is for and what effects the hazardous substance or new organism might have.
>
> • providing further information at the Authority's request.

3.8 It also provides:[20]

> D. SUBMITTERS
>
> • People making submissions on publicly notified applications have a responsibility to provide relevant information and a clear expression of their views on applications and their attitude to the risks posed.
>
> • Where scientific evidence or uncertainty is at issue, the submissions should indicate the scientific basis for any challenge to the information contained in the application.

3.9 It is not surprising that the methodology should focus on applicants providing sufficient information to the public given the methodology was to inform the "social, political and cultural value judgments" on applications, and the need for the Authority to be informed before it determined those matters.

3.10 In terms of the overall scheme, the decision making panel is an expert one and there is just one review on matters of law. This makes it important that the expert authority comes to its discretion with clear information and a clear understanding of what Parliament intended. The Supreme Court in *Wyeth (NZ) Limited v Ancare New Zealand Limited and Environmental Risk Management Authority* [21] quoted with approval the Authority's own approach to information (albeit in a slight different context):

> Within the bounds of the above statutory provisions, the Authority will require the release of <u>sufficient information to enable submissions on publicly notified applications to be made on an informed basis</u> and, more generally, for the Authority to be able to give reasons for its decisions.
>
> Applicants should provide a draft summary of information on the application that is suitable for release, and a version of the application and supporting information to which the public may have access, from which the confidential information has been excised.

[20] p 8, CB vol VI p6285.
[21] SC 57/2009. [2010] NZSC 46.

> This information must be sufficient so that it is clear what the application is for, what are the likely risks, costs and benefits, and what effects the hazardous substance or new organism might have.
>
> Underlining added

The special nature of GMOS

3.11 A key feature of GMOs that is not shared with other substances or new organisms under the HSNO Act is that their full characteristics are not known until they are created. While an application can propose a potential GMO, its precise characteristics cannot be known in advance. Our knowledge of the science, although now several decades old, while growing, remains imprecise. We do not know every aspect of the gene of the animal being modified, so the full implications for its genome and the interaction with proteins is not known and indeed the possible implications for every cell in the body of the animal. This is so even though modifications may be checked for stability before any insertion, and may be tested on other animals beforehand.[22] For example, even with the best of prior testing, it cannot be known in advance if a modification intended to be quite limited in a cow might result in a quite dramatic result, such as extremely abnormal growth in tissues or organs, perhaps at a level even life-threatening to the animal.

3.12 It is the quite unexpected outcomes that are the issue when assessing proposed GMOs. As the application itself states when it discusses potential beneficial effects:[23]

> "Taking into account that the purpose of the application is to produce therapeutic proteins and study gene regulation in livestock, AgResearch does not expect any direct environmental benefits to result from this application. The potential for beneficial serendipitous outcomes however cannot be discounted."

3.13 This makes proposed GMOs quite different from hazardous substances, or indeed existing organisms, whose characteristics are well known or comparatively well known since they have existed in the environment before. Each proposed GMO has never existed, and

[22] Application vol I pp1020-1021.
[23] Application CB vol I p1043.

usually, but depending on the modifications made, nothing quite like it could probably ever have existed within any evolutionary timescale.

3.14 The Authority has provided a succinct description of the process from development through to field testing and eventual release:[24]

> Genetically modified organisms (GMOs) are developed through genetic modification which involve a series of steps such as:
>
> • identification and isolation of the desired gene in a particular organism
>
> • purification and establishment of a delivery mechanism
>
> • transformation of the organism concerned that then is termed a GMO.
>
> These steps are normally carried out in laboratories, glasshouses or other facilities that meet containment standards commensurate with the level of risk and uncertainty involved in the transformation or development of GMOs. … the facility has to match the nature of the organism. If the organism being developed, for example, is a large animal, then the containment facility will be rather different from that required for a microorganism or plant.

3.15 The Act requires different information for each process and the information standards differ for each.

Specific provisions relating to GMOs

3.16 The Act provides for several different types of application for dealing with 'new organisms'.[25] Within that overarching structure, there is a particular regime for GMOs 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. These stages are:

(a) Importing a GMO

(b) Development (in and out of containment)

(c) Field testing in containment

(d) Controlled release

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[24] Key Concepts CB vol VI p6070.
[25] Section 39.

(e) Full release.

3.17 GMOs are defined as:

> "unless expressly provided otherwise by regulations, any organism in which any of the genes or other genetic 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:"

3.18 This covers both initial 'test tube' modifications to organisms, and all subsequent alterations through to for example the birth of a cow with modifications to its genetic makeup.

3.19 To 'develop' includes genetic modification of an organism.[26] Section 40(1) applies to applications to develop GMOs in containment.[27] The relevant parts are:

> 40. Application for containment approval for new organisms
>
> (1) Every person intending ….
>
> (b) to develop any new organism in containment; ….
>
> shall, before …. Developing, apply to the Authority for approval to... 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:

[26] Section 2 – but not including field testing of the GMO.

[27] This provision was amended by the HSNO Act 2010, s11, but since the application was made on the 4 November 2009, it must be processed as if the 2010 Act had not been enacted - s34(2)/2010, which refers to the assent date for the 2010 Act, which is the 19 April 2010. In any event, the 2010 Act does not alter the basic requirements of s40(1)..

3.20 "Any information prescribed" refers to forms. These are forms produced by the Authority. There are also user guides. These indicate what the terms used in the forms are meant to cover. The form itself sets out the prescribed information.[28]

3.21 These extensive requirements in relation to GMOs were added late in the development of the legislation. Until the committee stage, the information requirements for s40 were merely:

> 33 Applications 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 (genetically modified) new organism in containment –
>
> Shall, before importing or developing or testing, apply to the Authority for approval to import or develop that organism.
>
> (2) Every such application shall be in the prescribed form and shall include –
>
> (a) Information to identify the organism; and
>
> (b) All information relating to the effects of the organism known to the applicant; and
>
> (c) The purpose for which the approval is sought; and
>
> (d) Information about a containment system for the organism; and
>
> ---
>
> New
>
> (da) Information on all occasions where the substance has been considered by the government of any prescribed state or country or any prescribed organisation and the results of such consideration; and
>
> ---
>
> (e) Such other information as may be prescribed.

3.22 The amended provision therefore added extensive requirements to describe the host organism, project, experimental procedures, details of the biological material and expression of the foreign dna to be

[28] Discussed further below.

provided. Although he does not refer to section 40, in the committee stages when these further requirements were added, Dr Pete Hodgson, a member of the select committee which developed the legislation in bipartisan process commented:[29]

> Can I say very briefly in respect of new organisms that this legislation is conservative. Probably 10 years from now we will decide that it is too conservative. Probably when we learn about genetically modified organisms a little bit and become a little more comfortable with them, if indeed we will, we will decide that it is too conservative. It is certainly not appropriate to be anything other than very conservative at this stage of the genetically modified organisms debate. So the committee, and now the House is taking the decision that legislation that I believe to be very conservative will be passed into law.

3.23 Agreement on the changes to section 40 was unanimous.

3.24 Four main provisions apply to assessment by the Authority of an application to develop a GMO in containment. The main one, section 45, provides:

> 45 Determination of the application
>
> (1) After considering any application for approval made under section 40, the Authority ... may, in its discretion,—
>
> (a) approve the application if—
>
> (i) the application is for one of the purposes specified in section 39(1); 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) … the beneficial effects of having the organism in containment outweigh the adverse effects of the organism and any inseparable organism; 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 Schedule 3[30]; and
>
> (b) may include controls that provide for any other matters in order to give effect to the purpose of this Act.

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[29] 23 May 1996 NZPD (1996) p12693.
[30] Which sets out containment controls.

> (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.
>
> (4) In taking into account the adverse effects of the organism under subsection (1)(a)(ii), the Authority 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.

3.25 The additional matters which require consideration under section 43 are regulations (which are not applicable in this case) and the ability of the organism to establish an undesirable self sustaining population and the ease with which it could be eradicated.[31]

3.26 Section 44A applies because some of the research would be carried out indoors, and some completed outdoors within a containment facility.[32] It 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:
>
> (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

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[31] That is not in issue here.

[32] Section 2 provides that "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.".

(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."

3.27 Finally, for applications for development outside containment the Act requires cleanup of sites to occur.[33]

3.28 In terms of the specificity with which GMOs are to be identified, the Act suggests that reasonable certainty is required, because section 20 provides that a public register of all applications shall be kept by the Authority that specifies, inter alia, "a sufficient description of the substance or organism to uniquely identify that substance or organism".[34] This is consistent with the discussion of the register in *Wyeth (NZ) Limited v Ancare New Zealand Limited and Environmental Risk Management Authority* .[35]

Forms and User guides

3.29 The Authority also issues detailed forms for applications, as well as user guides as follows:

Prescribed information	Non-statutory user guides
Develop within a containment structure any Genetically Modified Organism (other than by rapid assessment) (application form NO-03)	Making an application to Develop within a Containment Structure any Genetically Modified Organism (ER-UG-NO3-2)
Develop in containment outside of a containment structure any genetically modified organism or regeneration of a new organism from biological material (application form NO-30)	Making an application to develop in containment outside of a containment structure any genetically modified organism or regeneration of a new organism from biological material (ER-UG-NO30-1)

[33] 45 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.
[34] S20(2)(b).
[35] SC 57/2009 paragraphs 50-52.

3.30 A further important document is Interpretations and Explanations of Key Concepts (April 2008) a non-statutory policy document that is relevant because it "outlines how the Authority will interpret some of the key concepts found in the Act and the Methodology".[36] The protocol "includes explanation of the key concepts relevant to the Authority's decision making. It provides further explanation of both definitions in Section 2 of the HSNO Act and the important concepts introduced in the Methodology but not described in the Act."[37]

3.31 The detailed forms, user guides and Interpretations and Explanations of Key Concepts ("Key Concepts") documents are non-statutory, and represent only the Authority's interpretation of the Act (so that the courts have the last word in any dispute) nevertheless they are official documents representing a considered interpretation of what the Act requires.

3.32 In terms of the definition of the organism under section 40, the forms set out what the Authority feels that it requires to undertake its statutory duties under the Act – and therefore what it considers Parliament intended.

3.33 "Organism" in s40(2)(a) and (b) in each case refers to the GMO, ie the outcome of a "host organism" being inserted with genetic material ("host organism" being defined as "an organism that is the subject of a genetic modification procedure" (s2). In other words, if the proposal is to genetically modify a cow, what must be identified is the modified cow. In other words, a simple one word answer 'cow' or even 'bos taurus" will not suffice for ss(2)(i).

3.34 The prescribed information in forms requires "Details of genetic modification; [Provide full details of the genetic constructs and modifications.]" User guides indicate the standard requirement for information in this area. For example, for developments in containment (ER-UG-NO30-1 05/04 p13):

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[36] Interpretations and Explanations of Key Concepts, Preface, page I CB Vol VI p6021

> Section 4.4 - Characteristics of the organism(s) to be developed
>
> In this section you should provide information on the main features or essential characteristics of the organism(s) to be developed. This information should be relevant to the identification of the risks of the organism (section 6), and you should note characteristics both of the host organism as well as any new characteristics introduced by the genetic modifications. These characteristics should all be identified in this section. Where possible provide references or additional information to support your statements. Published and non-published experimental data and information obtained from the indoor development phase of the genetically modified organism (if relevant) should be attached to this application to assist in risk assessment. An attached appendix of information concerning the characteristics of the non-modified host organism would be useful for risk assessment. ….
>
> The information can be presented in any format (text, table, and/or figures). This information will be used to develop exposure scenarios, assess risks, and specify potential containment conditions.

3.35 There are several discussions in the Authority's materials about the way to identify organisms in generic applications. The user guide for developments states (ER-UG-NO30-1 05/04 p9):

> 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.
>
> (underlining added)

3.36 The Key Concepts Guide provides this discussion:[38]

> A single application covering a variety of GMOs may be acceptable if the boundaries of the range of modifications envisaged are well defined. In identifying the range of modifications, the following parameters will need to be described: the taxonomy of the host

[37] Interpretations and Explanations of Key Concepts, Preface, page 1.1 CB Vol VI p6026
[38] Vol VI p6093 para 3.22.2.

> organism, the type of vector to be used and a detailed description of the source and function of any donor genetic material, the range of regulatory sequences and (any) selectable markers.
>
> In other cases, the application will be for a gene library, that is, for a host organism eg E. coli, of a particular strain containing a variety of plasmids carrying a variety of genes and will invariably be used for multiple purposes. …..
>
> In all cases, the information provided for the component parts, namely hosts, vectors and donors, will be sufficiently precise to enable ready determination of whether a specific GMO is covered by the organism description. The description may also exclude certain groups of hosts, vectors and donors where these exclusions will provide further certainty as to what is or is not covered.
>
> The Act also allows ERMA to grant approvals at any taxonomic classification, such as a genus, but provided that only organisms with identical genetic modifications fall within that approval.

3.37 This if a higher taxonomic level is being used, such as genus, the quid pro quo is a precise definition of the genetic modification being undertaken. This is what the words "same genetic modification" mean.

4. CASE LAW ON THE LEGISLATION

4.1 In *AgResearch v GE Free and ERMA* CA380/2009[39] GE Free challenged an application by Agresearch (which application was subsequently withdrawn) on the basis that it was so generic and deficient in information that the Authority ought not to have notified it. The Court of Appeal found that mere receipt of a potentially deficient application was a mechanical matter. It also noted:

> [57] We see the process as much more nuanced than that envisaged by Mr Salmon. 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.
>
> [58] We do not see that process as necessarily compromising public participation where public notification has occurred and parties other than the applicant have expressed an inclination to participate. Section 59 empowers ERMA to extend time for the making of submissions and one would expect that power to be invoked if submitters reasonably required time to comment on amendments to an application or proposed controls confining the scope of the application. If parties are on notice that proposals will develop in that

[39] [2010] NZCA 89

> manner during the consideration process, then they would be well advised to indicate their interest even in generic proposals to ensure that their voice will be heard if, on further clarification, the proposal raises issues in which they have an interest.

4.2 It is not clear if the Court of Appeal was aware that section 59 cannot be exercised in quite the way described. In any event, in this case the Authority did not seek further information or delay its consideration of the application to await further refinement of or information about the proposal.

4.3 Whether an application has sufficient information can be a reason for rejecting an application and that is a matter that can be and is directly raised by this appeal. Following the ruling in *AgResearch v GE Free and ERMA* the Supreme Court declined leave to appeal, but indicated that sufficient information, a matter raised in section 29 for hazardous substances, is implicit in section 45.[40]

4.4 In *Mothers Against Genetic Engineering Inc v Minister for the Environment* ("Madge")[41] the court determined that:

> [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.

4.5 The *Madge* case decision dealt with a generic application summarised as follows:[42]

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[40] Supreme Court minute, dated 7 July 2010: "This Minute is issued in response to the memorandum of counsel for the applicant seeking recall of judgment on the leave application. While the Court accepts that the reference to s 29 of the Hazardous Substances and New Organisms Act 1996 in its judgment of 29 June 2010 ([2010] NZSC 71) was strictly speaking in error, the first respondent is plainly right that what is express in s 29 is necessarily implicit in s 45. Accordingly the application for recall is dismissed.".
[41] 7/7/03, Potter J, HC Auckland CIV-2003-404-673 at p 68.
[42] from the 02028 application p7.

> This application is to develop genetically modified cattle that possess either exogenous genes controlled to express novel therapeutic proteins in their milk, or modifications of endogenous genes for altered phenotypic expression of products. Of all systems capable of expressing genetically modified proteins, the cow mammary gland is necessary because of the high-protein output and the ability to produce correctly processed functional proteins.
>
> The application is on a "project" rather than single organism basis. We have defined specific parameters of the project to ensure that risk is managed. These parameters include a single recipient type (cattle), limited donor species (cattle, sheep, goat, deer, mice, copy human), limited types of modification (deletion, insertion, deletion and insertion), a restricted number of modifications, containment of Tg and GMO to experimental sites, a research program to account for all insertions of Tg DNA and monitoring of genetic modification in microorganisms at disposal sites to ensure no escape of functional Tg genes. The potential risk for the classes of genes defined does not vary between individual genes within the class, and we note that genes we will transfer are already in the environment and fall into the low risk category as defined by the HSNO (Low-Risk Genetic Modifications) Regulations, 1998. Genes encoding toxins, allergens or human virus receptors will not be used in transgenesis.

4.6 The comments in *Madge* can be contrasted with the comment in the Court of Appeal case:

> If, as Mr Salmon suggested, AgResearch's applications are so generic that they involve an effective delegation by ERMA of its decision-making role to AgResearch (about which we express no view) and if that remains the case when the s 45 decision is to be made, one would expect that ERMA would not be satisfied that the application was capable of being approved under s 45.

4.7 In this case there seems to be no disagreement about the breadth of the application. It is submitted that given that breadth, the requirements of section 40 and the approach of the Act mean that it is not one that Parliament intended the authority to assess so that granting it effectively amounts to a delegation.

Legislative summary

4.8 In summary, the legislation is risk adverse. It is not a no risk statute. The concern in this case is the overall architecture set by Parliament within which risk was to be assessed, including in particular information requirements.

4.9 There are 2 key aspects to this, given the uncertainty inherent in GMO development:

(a) The Act takes a proposed GMO by proposed GMO approach. The overall approach of the Act, the requirements of section 40, Parliamentary debate, and the user guides confirm this.

(b) The Act requires detailed information about proposed GMOs. Section 40 requires it and again the user guides confirm it. The methodology requires extensive and detailed information about the particular substance or organism proposed in order for the cost and benefit assessment to be undertaken.[43]

4.10 The legislation in its final form created this quite separate regime and information requirements for proposed GMOs, which the earlier bill did not.

4.11 The High Court decision in the *Madge* case does not upset these requirements, since it retains the proposed GMO by proposed GMO approach.

4.12 The Court of Appeal decision makes it clear that generic applications run the risk of essentially seeking delegation of the decision making powers of the Authority.

5. WHAT AGRESEARCH APPLIED FOR

5.1 The application seeks to "develop in containment genetically modified goats, sheep and cows to produce human therapeutic proteins, or with altered levels of endogenous proteins for the study of gene function, milk composition and disease resistance." The research will take place in a containment facility at Ruakura.

5.2 The adequacy of the description of the host animals, and the location of the containment facility are not in issue. The concerns are the description of the genetic materials that may be used, and the related purpose.

[43] The methodology nowhere displaces, nor could it displace the GMO by GMO approach..

Purpose

5.3 In terms of the purpose, the application is extraordinarily wide, seeking biopharming for any and all diseases.[44] Human therapeutics is not defined. The ordinary meaning of that term includes all diseases in existence today, known and unknown. This includes:

(a) All viral and bacterial diseases

(b) All infectious diseases

(c) All sexually transmitted diseases

(d) All mental disorders.

(e) All dependency disorders (eg alcoholism, drug)

(f) All rare disorders, genetic disorders, and diseases that might affect particular populations, such as Maori.

(g) Future diseases not yet in existence. This would include, for example, new animal to human diseases. By way of example, there is debate about whether HIV is a recent animal to human disease. It includes any new environmental diseases ie diseases arising from changing environmental conditions.

5.4 New diseases may include new agents and new pathways for transmission. For example, we have known about viruses as a pathways for about 100 years, but subviral or protein only transmitters, prions, were unknown until a couple of decades ago. Yet they are the cause of a number of diseases in a variety of mammals, including bovine spongiform encephalopathy (BSE, also known as "mad cow disease") in cattle and Creutzfeldt–Jakob disease (CJD) in humans.

[44] See also wide discussion in the application at p45-47 vol I pp1045-1047 concerning potential benefits of the application.

5.5 It is not even clear if better understanding or investigation of possible diseases is covered. In other words, does a disease have to be identified and defined in appropriate scientific literature before work on it can begin under this approval? This is important if a new or poorly understood disease turns out to have virulent characteristics.

5.6 In terms of the secondary purpose the application is also very wide. The intention is to "alter levels of gene activities and proteins for the study of gene function, milk composition and disease resistance".[45] This is further described as follows:

> "Gene function
>
> The function of a gene can best be studied by loss and gain of function experiments which involves deleting the gene from an organism (or deleting its function via the expression of antagonistic genes) or switching it on in abnormal regions or at abnormal times or at higher levels. Such experiments requite the modification of the organism on a genetic level. While this type of work is commonly performed in mice, mice are not suitable for a myriad of scientific, medical and veterinary questions."

5.7 In terms of purpose, this seeks permission to alter livestock in any manner. In particular, the purpose of altering genes to simply study 'gene function' provides the widest possible breadth to the application. The reference to disease resistance presumably includes all human diseases, but is not limited to that.

Modifications

5.8 In terms of the types and sources of genetic material to be used and therefore the modifications that might be undertaken, Appendix II sets these out. It runs to over 700 pages. Dr Carman's undisputed evidence on that matter was:[46]

> "The applicant has not provided any specific information about which one of many possible promoter sequences it will use, which one of many possible terminator sequences it will use, which of many possible marker genes it will use, whether the marker genes used will make the animals resistant to antibiotics (and if so, which antibiotics), nor has it specified which other specific genes will be used. Instead, the applicant has provided an enormous list of thousands of organisms from which it may use millions of different

[45] CB Vol I p1006.
[46] Dr Carman was a witness called by GE Free, who appeared by telephone. Her full evidence is at CB vol IV p4435, a transcript of her appearance is at CB vol V pp5038-5044.

> DNA sequences and/or genes. Indeed, the applicant has given a wish list of organisms or sections of DNA that includes hundreds of different strains of E. Coli bacteria, hundreds of different plasma vectors, hundreds of different animal species, tens of different invertebrate species, a species of frog, tens of different fish species, over a thousand different plant species, tens of fungi species, tens of bacteria species, tens of protozoa species, thousands of different viruses and hundreds of mammalian cell lines (including human cell lines). Given that several sequences/genes may be used together in the gene cassette, the applicant is in fact asking for approval to make any number of many millions of different gene cassettes and to insert them into recipient animals. This means that the applicant is asking permission to make a subset of possibly millions of different genetically modified animals."

5.9 At the hearing, submitters asked for a description of the GMO – as opposed to the host.[47] The response made it clear that the applicant saw this as a generic application supported by the High Court decision in *Madge*.[48]

5.10 The list in Appendix II is presumably broad because Agresearch has not limited itself to particular diseases. One gets the impression from the Appendix that most if not a large section of the organisms which have been studied in one way or another for their genomes have been included.

5.11 Dr Carman's conclusion (with which the Authority obviously did not agree) was that:

> "Due to the lack of specificity of the applicant, there is no way that I, or I believe any scientist, could do a safety assessment on the resultant proteins. One cannot do a safety assessment on something that is unknown. I would need to have information such as which specific genes and other sections of DNA are to be brought into the recipient organism, how they will be placed relative to each other, how they will be inserted into the recipient animal, which proteins are produced in the animal as a result, how those proteins differ in their final form from the "native" proteins that occur in the donor organisms, amongst others."

5.12 It is certainly clear that no specific GMO or even GMOs with a particular modification or type of modification could be named from the application. Indeed, that seems to have been Agresearch's specific intent, because its application makes it clear that it is interested in any biopharming opportunities that might arise.[49]

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[47] CB vol V p5024.
[48] CB vol V pp5024-5026, pp5140-5141
[49] See articles in Vol I tabs 3, 4 and 5..

5.13 The application attempts to undertake a detailed analysis of risks of escape of whole organisms or hereditable or other material at pp32-37.[50] There is an assumption in places[51] that previous experience with containment of genetically modified livestock means that particular GMOs do not need to be identified and the diseases which will be worked on need not be defined. For example, the analysis of possible outcomes if escape occurred might well be different if livestock were being modified to produce a product to treat a new, virulent and highly infectious disease.

6. WHAT THE AUTHORITY DECIDED

6.1 ERMA approved the application essentially as presented. The decision does not identify any particular GMO or types of GMO. Instead, in a diagram in the decision, ERMA sets out its thinking about how it sets limits to the GMOs that might be produced.[52] This diagram takes the form of an inverted pyramid, with the host organism and modifications forming the two largest blocks in the pyramid, the technique used provides further refinement, and the trait – which is the project description – providing the final limit. No particular organism or organisms are identified.

6.2 Potential pathways for escape from outdoor containment are examined.[53] These includes examples given by submitters, such as the escape of a foot and mouth virus in 2007.[54] In particular ERMA notes the controls that:[55]

> "The Committee further noted that none of the approved organisms are disease causing, and that there is a specific exclusion on the approved organism description preventing modifications that introduce the complete coding sequence of known human or animal virus receptor genes. Furthermore, the Committee noted that none of the proposed modifications will enhance the ability of the organisms to escape from containment."

[50] CB vol I pp 1032-1037.
[51] CB vol I p1032.
[52] 4.3.1 "The Committee has used a strategy illustrated in Figure 1 to limit the types of GMOs that can be developed under this approval" p3141. Underlining added.
[53] CB vol III pp3146-3152.
[54] CB vol III p3146.
[55] CB vol III p3146.

6.3 As noted, Dr Carman disputes that such sweeping assessment can be made in the absence of further information about what the modifications might be. Her approach accords with the requirements in section 40 which Parliament has set.

6.4 An assessment of potentially significant adverse effects on human health and safety is made, including the assessment that: [56]

> "6.2.4. The Committee noted that the applicant has stated that there is a theoretical possibility of the creation of a new viral disease, but that the applicant will not use any known disease causing organisms. Furthermore, the applicant has stated that any gene or protein of interest will not be introduced to goats, sheep or cattle until the consequences of that genetic modification are known."

6.5 The use of the word 'known' in that statement is a reflection of the uncertainties in this field. As noted, Dr Carman takes a different view. Again, it is an expression of the comfort which the Authority's panel of experts feel about what is known or unknown, but does not reflect Parliament's intention to take a more limited approach by requiring modifications to be identified.

6.6 The same issues arise for the conclusion that:[57]

> "6.2.21. The Committee noted that while the disposal of denatured milk through spraying on fields will expose soil biota to GM material, none of the recommended modifications (including the use of antibiotic resistance genes) has the potential to increase the likelihood of HGT."

6.7 That statement relies on the notion that millions of unknown modifications can be subject to such a sweeping assessment. That may or may not be the case (scientists such as Dr Carman are more cautious), but it is not a level or breadth of assessment that Parliament had in mind when it passed the Act including the identification requirements of section 40.

6.8 The social economic and cultural matters are discussed under the heading "Assessment of potentially significant adverse effects on

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[56] CB vol III pp3153-3154.
[57] CB vol III p3155.

society and communities"[58] and separately an "Assessment of potentially significant adverse effects on the market economy"[59] In each case the panel found no discernable adverse effects, despite being unaware of the particular diseases and particular modifications that might be undertaken. For example, potential damage to NZ's clean green image is assessed against animals escaping or the research becoming known about.[60] But that would depend to a significant extent on the disease which is being researched, which is not assessed, because it is not of course known.

6.9 Overall, the key deficiencies of the decision are:

(a) The failure to identify any particular modifications. The decision simply refers to the possibilities contained in Appendix II and uses the inverted pyramid diagram as described.[61]

(b) Assessment of the possibility of escape from containment in the absence of any particular modifications being identified. There is a clear contrary scientific view about the validity of that approach, and Parliament intended the assessment to occur with organisms that had been identified.

(c) Assessment of economic, social cultural effects without identification of particular genetic modifications to be undertaken in an application covering the whole range of human diseases.

(d) The Authority has adopted an approach that lack of adverse effects over time from GMOs in other areas means that such an extensive application can be entertained without information required in section 40 being provided. Parliament did not intended such wide ranging applications and such

[58] CB vol III p3159.
[59] CB vol III p3161.
[60] CB vol III p3162.
[61] para 2.5.1 CB vol III p3134.

wide ranging assessments of possible risk to be undertaken. If it had intended that this might be possible, it would not have set out the specific requirements in section 40. These requirements to be specific about the proposed modifications were intended to place a limit on each application.

(e) In addition, Agresearch has simply failed to provide the information required by the Act.

(f) The Authority is simply assessing risk of health and safety well beyond parameters set by Parliament, and it logically unable to assess social and cultural risks with such a wide application.

(g) A further consequence is that most submitters felt unable to engage and make meaningful comments or suggest meaningful controls on the scientific, but also the social, economic and cultural aspects of the application. That also is contrary to the intention of the Act, and in particular the intention that the methodology allows societal values to be balanced and not left entirely to expert assessment.

6.10 The Authority seems to be unaware of the irony of its comment in the decision that:[62]

> "Through the HSNO Act Parliament has decided to provide for genetic modification to occur in New Zealand on a case-by-case basis, when the beneficial effects of the GMO outweigh any adverse effects. As a result the Committee can take into account only the effects which are specific to this application in reaching a decision. General views on genetic modification are not effects specifically related to this application."

6.11 The Authority's expert panel has essentially determined that the specific requirements for identification under section 40 do not have to be met expect in the most general way, and not in the spirit with which they were introduced. It has substituted its view for the requirements of the statute.

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[62] para 6.1.4 CB vol III p3152.

6.12 In so doing it has essentially delegated an aspect of its decision making to Agresearch. Under this approval, that research body will determine what diseases and classes of diseases it wishes to research, and what particular treatments it will seek to deliver via milk proteins. The word 'proteins' (which includes enzymes) of course covers an enormous range of possibilities given the millions of proteins that exist in animals.

7. CONSIDERATION OF ALTERNATIVES

7.1 In terms of section 44A ERMA determined that:

> "6.3.3 The Committee considered that while cell culture may be used to produce therapeutic proteins, this would not meet the stated research objective. It further noted that with controls in place, no significant adverse effects on human health and safety or the environment were identified from this research.
>
> 6.3.4 Therefore, the Committee did not identify any alternative means of achieving the research objective that would have fewer adverse effects."

7.2 To consider both biological risk (health and safety) and social, cultural and economic risk (the environment) under section 44A the Authority required:

(a) Knowledge of the particular diseases in issue and their virulence, infectious ability etc. It may make a difference to modify cows to produce proteins relating to a future serious infectious disease as opposed to proteins to deal with relatively well understood and non-infectious genetic disorders.

(b) Knowledge of the particular diseases to assess their social and cultural implications. The association of NZ livestock with research into, for example, a future controversial human disease, might have significant social, economic and cultural impacts, perhaps threatening NZs overseas reputation, being particularly offensive to some cultural group.

(c) Identity of the particular diseases and other programmes to treat them, and their risks, in order to consider whether the above risks could be avoided by not having research undertaken by way of proposed GMOs.

(d) Knowledge of the proposed modifications to understand what physical outcomes by way of proteins, altered cells, tissues, organs might be created, how they might express themselves in the GMO, and methods of transference to other organisms "in or around" the open air site. The concern is presumably all methods that altered cells, tissues, or the livestock itself might transfer material to other livestock, humans, plants, insects etc.

(e) Knowledge of the diseases involved and current methods to control them (cell culture or other methods) and whether proteins in milk or some other approach provided the required result.

7.3 That assessment was not undertaken. In particular, there is of course no way in which the Authority can apply this test to currently existing but unknown diseases, nor to diseases not yet in existence. For example, new diseases which may have some feature which makes cell culture or a means other than protein in milk much better able to treat them.

7.4 Rather than undertaken the assessment, the Authority has determined that, no matter what modifications will be produced for what diseases, for all possibilities the adverse effects will be so low that assessment is not required. That is not the task that Parliament set.

8. CONTROLS

8.1 The application mentions limits biological limits to the modifications to be undertaken at pp14-20.[63] The application discusses proposed physical controls at pp51-54.[64]

8.2 There are 3 issues with the controls imposed. First, the Authority used controls to purportedly narrow the scope of the application before assessing risk and determining it, something which the Act does not contemplate.[65] The Authority said:

> "Section 45(2)(b) empowers the Committee to impose controls on an approval that provide for matters other than those specified in Schedule 3 of the Act, in order to give effect to the purpose of the Act. In addition, section 45(4) requires the Committee to take into account in the assessment of the adverse effects all the controls to which the organism would be subject if the application were approved.
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> Therefore, controls may be imposed to define and limit the scope of the organisms to be considered, and these need to be set before the application is assessed under section 45. As a result, the Committee has considered the scope of the organisms described in the application, and whether it is necessary to narrow this description via the imposition of controls." (underlining added)

8.3 In law, that cannot be the correct order of approach to assessment. The panel, like submitters, must assess the application in its own terms. Conditions may be imposed to limit the effects of the application. Applying controls first, to redefine the application before it is assessed for risk means that the panel ends up assessing a proposal that neither the applicant nor submitters have ever seen.

8.4 In any event, having taken that approach, the controls which are imposed do not limit the application in particular:

(a) The purported control via the very wide purpose of the proposal is not a control at all;[66]

(b) The purported controls via imposition of limits simply repeat the limits in the proposal – so no narrowing of the proposal

[63] CB vol I pp1014-1020.
[64] CB vol I pp1051-1054.
[65] para 4.1.2 CB vol III p3140.

was actually undertaken.[67] Consequently, the controls do not alter the criticisms of the decision noted above.

9. CONSULTATION WITH MAORI

9.1 The provisions in the legislation relating to Maori begin with section 5(b) of the HSNO Act requires that the Authority, when exercising functions under the Act, will recognise and provide for:

> "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."

9.2 Issues relating to Maori communities are encompassed by it:[68]

9.3 Section 6 provides that the Authority shall "take into account" inter alia "the relationship of Maori and their culture and traditions with their ancestral lands, water, sites, waahi tapu, valued flora and fauna, and other taonga."[69]

9.4 Section 8 provides that "all persons exercising powers and functions under this Act shall take into account the principles of the Treaty of Waitangi (Te Tiriti o Waitangi)." The Authority accepts that under this provision it is required to "act reasonably and in good faith, and to make informed decisions that actively protect Māori interests."[70]

9.5 Under Part 4A, a body of between 4 and 8 persons is appointed by the Authority as a committee, called Nga Kaihautu Tikanga Taiao, whose function is to provide, from a Maori perspective, "advice and assistance to the Authority as sought by the Authority on matters relating to policy, process, and applications."[71]

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[66] para 4.3.3 CB vol III p3142.
[67] paras 4.3.4-4.3.7 CB vol III p3142.
[68] ERMA itself has said this also: CB vol VI pp 6346 and 6351.
[69] Section 6(d).
[70] CB vol VI p 6347.
[71] section 24B.

What are the requirements re consultation?

9.6 Several cases under the Resource Management Act 1991 have suggested that similar provisions in that Act to sections 6(d) and 8 place a duty to consult on applicants and consent authorities. The RMA 1991 has been amended to make it clear that that is not the case.[72]

9.7 In *Bleakley v ERMA*[73] the High Court held that to "take into account" the matters specified in section 6 is "an obligation to consider the factors concerned in the course of making a decision to weigh it up along with the other factors-with the ability to give it considerable, moderate, little, or no weight at all as in the end in all the circumstances". This would also apply to the requirement to "take into account" the principles of the Treaty of Waitangi in section 8.

9.8 Whether or not there is a duty to consult under the HSNO Act, there is a requirement for the Authority to have information about Māori views sufficient to inform itself of the potential effects of a particular proposal before it. The Authority recognises this, and has established a protocol for assessing Māori and Treaty of Waitangi information, pursuant to sections 6(d) and 8 of the HSNO Act. It provides that:[74]

> "Where risks have a local impact, then consultation is conducted with local tangata whenua (iwi/hapū/whanau) unless the Authority, in consultation with Ngā Kaihautū, determines otherwise. The Authority expects local consultation to be carried out by the applicant. Where risks potentially involve issues of significance to Māori on a national scale, as may be the case for the release of new organisms and the import or manufacture of particular hazardous substances, nation-wide consultation is likely to be required."

9.9 This approach is accepted by the Authority in its decision.[75] There is no suggestion in the statute or any case law to support the idea that consultation over proposal X will suffice for consultation over a

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[72] section36A RMA.
[73] [2001] 2 NZLR 213 (HC) at p 27.
[74] CB vol VI p 6348.
[75] CB vol III p3156 para 6.2.24 Consultation with Māori is a means of giving effect to sections 6(d) and 8. Section 6(d) requires the Authority, when exercising functions under the Act, to specifically take into account the relationship of Māori and their culture and traditions with their ancestral lands, water, sites, waahi tapu7, valued flora and fauna, and other taonga8. Section 8 requires that the Authority take into

different proposal Y. The High Court in *Bleakley* indicated that the significance on the effects on Māori will depend on the fact of each case – or application.[76] The requirements of consultation set out in *Wellington International Airport Limited and others v Air New Zealand* do not support such an approach.[77]

The consultation and the Authority's decision

9.10 The Application makes it clear that only consultation with the landowners was undertaken on this proposal.[78] Agresearch directly cited the national consultation on a previous application in support of this one.[79]

9.11 Nga Kaihautu noted that there had been no national iwi/Maori consultation by the applicant, on the basis that:[80]

> "as the four previous applications and the current application are similarly aligned, there is no need for pre-application consultation with iwi/Maori in this case. It is noted that the applicant did consult with local iwi, Ngati Wairere and Waikato-Tainui, when preparing this application.
>
> Although Nga Kaihautu acknowledges the extensive pre-application consultation carried out by the applicants for the four applications

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account the principles of the Treaty of Waitangi (Te Tiriti o Waitangi). Consultation allows the Authority to seek information related to these matters, and to keep Māori informed..

[76] *Bleakley* p10.

[77] [1993] 1 NZLR 671, at p. 675 "Consultation must allow sufficient time, and a genuine effort must be made. It is a reality not a charade. The concept is grasped most clearly by an approach in principle. To "consult" is not merely to tell or present. Nor, at the other extreme is it to agree. Consultation does not necessarily involve negotiation toward an agreement, although the latter not uncommonly can follow, as the tendency in consultation is to seek at least consensus. Consultation is an intermediate situation involving meaningful discussion. Despite its somewhat impromptu nature I cannot improve on the attempt at description, which I made in *West Coast United Council v Prebble*, at p 405: 'Consultation involves the statement of a proposal not yet fully decided upon, listening to what others have to say, considering their responses and then deciding what will be done.' Implicit in the concept is a requirement that the party consulted will be (or will be made) adequately informed so as to be able to make intelligent and useful responses. It is also implicit that the party obliged to consult, while quite entitled to have a working plan already in mind, must keep its mind open and be ready to change and even start afresh. Beyond that, there are no universal requirements as to form. Any manner of oral or written interchange which allows adequate expression and consideration of views will suffice. Nor is there any universal requirement as to duration. In some situations adequate consultation could take place in one telephone call. In other contexts it might require years of formal meetings. Generalities are not helpful.".

[78] CB vol I p1031. "Consultation. In the course of preparing this application AgResearch has not identified a specific need for consultation with Maori or stakeholders as the scope of activities and the specific facility being used have been the subject of extensive consultation previously and regular monitoring meetings for the current approvals have not identified any new issues requiring specific mitigation. AgResearch has also undertaken consultation with Maori on a National basis in early 2008 prior to submitting previous applications with a wider scope of activities and location potentials which were then subject to a public submission process and are now subject to legal proceedings, (see Appendix VI for a summary of the outcome of that process).".

[79] Application p 44, CB Vol I p 1044.

[80] CB vol III p3019.

> mentioned earlier, Nga Kaihautu believes that that process could have been better and is in general agreement with the observations made in the Jolly report. That is, overall the process and intention of the applicant was good, however, the timing of all the consultation hui was problematic and not conducive to meaningful consultation by iwi/Māori."

9.12 And in concluding the committee noted:[81]

> "Nga Kaihautu believes it is not good practice to assume that **only** those issues raised in one set of circumstances are of consequence in another similar set of circumstances. That is, it does not necessarily follow that the only matters to be considered in relation to iwi/Maori in this case are those issues raised during the consultation on the four genetic modification applications.
>
> Although we do not endorse the consultation process from one application being used to inform the decision-making process in another application, Nga Kaihautu notes the good faith with which the applicant approached the consultation process for the four broad applications. Nga Kaihautu is also aware of the extent of the pre-application consultation carried out and that despite the applicants good intentions, short-comings were identified in that process."

9.13 The Authority in its decision endorsed this approach, accepting that the consultation on a previous application had been sufficient. It commented:[82]

> "6.2.29 Nevertheless, the Committee has imposed a control requiring the establishment of an iwi monitoring group to provide sufficient opportunity for ongoing consultation and enable the active monitoring of intangible effects (**Control 13**). The Committee expects the applicant (with agreement from Ngāti Wairere and Waikato-Tainui) to invite other relevant and interested Māori groups to be involved in this monitoring group so that information about the science can be shared and made available to all those in the region with an interest in the research.
>
> 6.2.30 Finally, given the complexity of the technology and the potential uncertainty regarding intangible effects the Committee **recommended** that the applicant be invited to participate in future Māori National Network hui or wānanga convened by ERMA New Zealand. This would provide the opportunity for the applicant to provide updates and information about the research whilst also enabling a broader Māori audience to participate in ongoing discussion and exploration of the issues involved." (underlining added)

9.14 The unknown matters with the application in this case are noted above. Briefly, although the application is for development in containment in fields in Hamilton, and it is not intended that the modified livestock leave the research facility, it may nevertheless be offensive if, for example, it was intended to modify cows to produce some protein in

[81] CB vol III p3021.
[82] CB vol III p3157.

milk to treat or assist with the treatment of a disease that particularly affected Maori – whether currently known or unknown. And since any kinds of modification are also possible to study 'gene function', the possible modifications are limited only by the large Appendix II possibilities.

9.15 The conclusion of ERMA that the complexity of the technology and the potential uncertainty regarding intangible effects called for an ongoing discussion in monitoring groups is an acceptance that ERMA did not have sufficient information to fulfil the requirements of sections 6(d) and 8.

9.16 It is submitted that ERMA has wrongly:

(a) Proceeded to assess these aspects of the application in the absence of information required by the Act without which that assessment cannot be made;

(b) Assumed without this information that no greater than local consultation was required;

(c) Recognized that wider than local consultation was required, but explicitly relied in its decision on the results of consultation for a different application – which was in any event withdrawn;

(d) Essentially delegated the assessment of effects on Maori to future hui.

9.17 The problem has not been remedied by submissions since submitters complained about the lack of information in the proposal and the problems of relying on previous consultation.[83] Nor could any comments remedy the problem that the application is limitless in terms of diseases that might be studied and treatments that might be

[83] CB vol III p 3156, "6.2.26 A number of submitters noted concern regarding the lack of specific consultation with Māori for this application. During the hearing these concerns were emphasised by the Ngāti Koroki Kahukura Trust, Te Waka Kaiora and Te Kōtuku Whenua Consultants. They, along with Ngā Kaihautū Tikanga Taiao, called for the Māori Reference Group (established for the previous AgResearch applications) to be reconvened.".

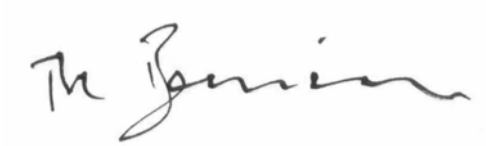
researched, as well as 'gene function' experimentation that might be undertaken.

9.18 The complaint of the submitters in this consultation was the same as in the previous application which was withdrawn. That previous consultation cannot therefore be seen as in some way fulfilling the requirement to be suitably informed.

10. RELIEF

10.1 Section 126 and the Act do not explain what powers the court has where it finds the Authority has acted in error of the law. In *Bleakley v ERMA*, where there was a failure in the decision of the Authority to identify how the criteria in the Act and methodology applied, the matter was remitted to the Authority to reconsider. The court noted that it was a matter for the Authority whether further submissions should be held or further hearings "dealing with (for example) any updating material."[84] In this case the allegation is that the application requires amendment to meet the basic information requirements of the Act. In those circumstances, the applicant should be invited to amend the application in line with any comments from the court. This would necessitate an amended application being filed and the opportunity for fresh submissions being given.

DATED AT Wellington this 8th day of November 2010



TH Bennion/F Khan

Solicitor for the Appellant

[84] [2001] 2 NZLR 213 (HC) at paragraph 327.

TO: The Registrar, High Court, Wellington

AND TO: The First and Second Respondents, s128 party