IN THE HIGH COURT
WELLINGTON REGISTRY

UNDER THE	Hazardous Substances and New Organisms Act 1996
BETWEEN	**GE FREE NZ IN FOOD AND ENVIRONMENT INCORPORATED**
	Plaintiff
AND	**ENVIRONMENTAL RISK MANAGEMENT AUTHORITY**
	First Defendant
AND	**AG RESEARCH LIMITED**
	Second Defendant

SUBMISSIONS OF COUNSEL FOR PLAINTIFF

23rd of FEBRUARY 2009

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1. BRIEF SUMMARY OF ARGUMENT

1.1 The Hazardous Substances and New Organisms Act 1996 ("HSNO") sets out basic information requirements that applications to create and test Genetically Modified Organisms must fulfil so that the Environmental Risk Management Authority ("ERMA") and potential submitters are aware of the scope of the application and have information to assess the risks arising.

1.2 AgResearch has made 4 'generic' and linked applications:

(a) GMC 7012: importing livestock and laboratory animals into containment

(b) GMD 8012: developing livestock and laboratory animals in containment

(c) GMD 7074: developing livestock in outdoor containment

(d) GMF 7001: field testing livestock in outdoor containment

1.3 8012, 7074 and 7001 are the particular focus of these proceedings, but the information concerns also affect 7012, in terms of the identification of GMOs required by the Act.

1.4 The applications are generic in the sense that they seek to import, develop and test and range of possible GMOs. GE Free New Zealand Incorporated ("GE Free") is not contesting the ability to apply for a generic application. The concern is that the applications lack essential information required under the HSNO Act, such that they should have been returned to the applicant for further information before they were notified to the public under section 53 and submissions sought.

1.5 There are several key omissions, from which other problems flow. The key omissions are:

(a) In relation to all applications, failure to identify the GMO with any certainty;

(b) In relation to the development and field test applications, failure to specify any locations and seeking any location; and

(c) In relation to the field test, failure to identify any field tests.

1.6 These proceedings are not a counsel of perfection or nit-picking around the information details of these applications. The allegation is that they are simply lacking basic material so as to prevent anyone, expert or lay, understanding their scope and providing specific information or comment to assist in managing the risks arising.

1.7 The lack of essential information has had the practical outcome that, while many submissions have been received, the overwhelming majority have indicated that there is insufficient information to make sensible comments on the applications.

1.8 The relief sought is that the applications be withdrawn from the process and referred back to ERMA and the applicant to fulfil the statutory requirements.

2. FACTUAL BACKGROUND

2.1 GE Free has been involved in previous litigation and is in regular contact with ERMA about all aspects of policy as well as particular applications. It is a submitter on these applications.

2.2 AgResearch is a research institution based in Ruakura. The 4 applications are described by AgResearch as follows:

> GMC07012: Import into containment livestock and laboratory animal species (live animals, sperm, embryos - importation of live animals into containment will be rare). Maintain animals for research, breeding and production. Import animal cell-lines (including human and monkey cell-lines), E. coli and yeast for use in the development (genetic modification) of livestock and small animals under GMD07012 and GMD07074.
>
> GMD08012: Develop livestock and laboratory animals in indoor containment. Maintain those species for research, breeding and production. Develop animal cell-lines (including human and monkey cell-lines), E. coli and yeast for use in the genetic modification of livestock and laboratory animals.
>
> GMD07074, this application: Develop livestock species in outdoor containment. Maintain those livestock for research, breeding and production.
>
> GMF07001: Field test livestock in outdoor containment. Maintain those livestock for research, breeding and production.

2.3 The applications are generic – both of and between themselves. There is much common information between them. This is an important point as will become apparent later in these submissions.

2.4 ERMA formally received the applications on the 9 July 2008.

2.5 ERMA sought further information under section 52 on 21 July 2008. Answers were received from AgResearch on 29 July 2008.

2.6 ERMA publicly notified the applications on the 13 August 2008.

2.7 When submissions closed on the 30 October 2008, 1760 submissions had been received. 1232 or 70% of those submissions contained an explicit statement or statements that the applications are too vague or lack sufficient information for the submitter to make a meaningful submission. These are referenced in Ms Bleakley's second affidavit. They include expressions of concern about a lack of information from groups including Federated Farmers and Waikato-Tainui.[1]

3. RELEVANT PARTS OF THE HSNO ACT

3.1 This part of the submissions outlines key features of the HSNO Act relevant to the proceedings. The following section deals with the legal tests that apply to notification of applications and the provision of sufficient information.

3.2 The Act requires approval for many 'new organisms' of which GMOs are a subset. GMOs are defined as:

> Genetically modified organism means, 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:

3.3 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.

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[1] Refer Bleakley second affidavit, para 2, exhibit "A".

3.4 The Act provides for several different types of application for dealing with 'new organisms'. 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

(e) Full release.

3.5 To 'develop' (s2) means:

> develop,—
>
> (a) in relation to organisms other than incidentally imported new organisms,—
>
> (a) means—
>
> (i) genetic modification of an organism:
>
> (ii) regeneration of a new organism from biological material of the organism that cannot, without human intervention, be used to reproduce the organism:
>
> (iii) fermentation of a micro-organism that is a new organism; but
>
> (b) does not include field testing

3.6 And "field test" is defined as:

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

3.7 ERMA has provided a succinct description of the process from development through to field testing and eventual release (Key Concepts p 3.11):

> 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.
>
> If the desired outcome of the transformation and development is achieved, the GMO may be taken out of the laboratory or glasshouse and into the environment for further evaluation. This evaluation outside the contained laboratory or glasshouse constitutes a *field trial* because it is evaluating the organism *under conditions similar to those of the environment into which the organism is likely to be released* as stipulated in the definition of *field test*. The Act requires a greater level of public involvement with field trial decisions because field trials represent inherently less contained conditions, i.e. no physical laboratory and a larger scale.
>
> If an applicant intends to undertake all of the steps identified above the Authority will expect the applicant to submit both a development and field trial application or a combined application.

3.8 A field test involves "research procedures aimed at providing statistically valid results about the effects of the organism (including animal or herd performance)" (*Mothers Against Genetic Engineering Inc v Minister for the Environment* ("*Madge*") 7/7/03, Potter J, HC Auckland CIV-2003-404-673 at p 68). That case confirmed that field tests will usually take place in release like conditions since field-testing will often precede a full release application.

3.9 The Act requires different information for each and the information standards differ for each. Section 40 deals with the importation, development or field testing of new organisms in containment.

3.10 For importing a new organism into containment (including GMOs) the application must include:

(a) any information prescribed;

(b) 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,

(c) information about the containment system for the organism." S40(2)

3.11 "Any information prescribed" refers to forms. These are forms produced by ERMA. There are also user guides. These indicate what the term used in the forms are meant to cover. The form itself sets out the prescribed information.

3.12 For developing a new organism which is a GMO in containment the application must also provide (s40(2)(a):

> (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:

3.13 The information requirements for a field test of a GMO in containment are different again, requiring in addition to (a) and (b) above:

> (i) The identification of the organism; and
>
> (ii) The purposes of the field testing …; and
>
> (iii) The genetic modifications of the organism to be tested; and
>
> (iv) The nature and method of field trials and the experimental procedures to be used; and
>
> (v) All the possible adverse effects of the organism on the environment.

3.14 The difference between a development and field test of a GMO being that the development creates a GMO (hence the focus on the details of the biological material to be used and the expression of the foreign DNA), while the field test begins with a stable GMO (such as a GM modified calf) and tests it for production of expected benefits, and any potential adverse effects on environment.

3.15 These information differences between a development and a field test of a GMO are important because they relate to the different requirements which each have to meet depending on the type of development or field test of the GMO. For example, when considering a development inside containment of a GMO where part of the development is outside containment, and for a field test of a GMO, ERMA must consider alternative methods to obtain the same research objectives (s44A(2)(b), and "any effects resulting from the transfer

of any genetic elements to other organisms in or around the site of the development or field test" s44A(2)(c) (also known as horizontal gene transfer – discussed further below).

3.16 Applications under s40 are determined under s45 which sets out a variety of requirements assessing risks of creating and holding the organism.

3.17 In addition, section 44A provides that for developments outside containment and field tests alternative methods of achieving the research objectives that have fewer adverse effects must be taken into account (s44A(2)(b)) as well as any effects from the transfer of stray genetic material "in or around the site" (also known as horizontal gene transfer).

3.18 Turning now to the detail of the information required under section 40 and associated regulations.

"Information prescribed"

3.19 The prescribed information is contained in applications forms under the Hazardous Substances and New Organisms (New Organisms Forms and Information Requirements) Regulations 1998 (SR 1998/218) – made under s140(1)(l) & (m).

3.20 ERMA also issues detailed forms for applications, as well as user guides as follows:

Prescribed information	**Non-statutory user guides**
Import into containment any New Organism that is Genetically Modified (application form NO-02G)	Making an Application to Import into Containment any New Organism that is Genetically Modified (ER-UG-02G-1)
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)
Field test in Containment any Genetically Modified Organism (application form NO-04)	Making an Application to field test in Containment any Genetically Modified Organism under the HSNO Act 1996 (ER-UG-NO-04-3 02/08)

3.21 A further important document is *Interpretations and Explanations of Key Concepts* (May 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".[2] 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."[3]

3.22 The detailed forms, user guides and *Interpretations and Explanations of Key Concepts* ("Key Concepts") documents are non-statutory, and represent only ERMA'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.

"Information on all occasions where the organism has been considered"

3.23 The organism refers to the GMO. The requirement is to provide information on "all occasions where the organism has been considered by the government of any prescribed state or country, or by any prescribed organisation".

3.24 This formulation is used at several other places in the Act dealing with hazardous substances (s28(2)(e), s31(2)(d), and for new organisms s34(2)(b) [for conditional release of new organism] 38A(2)(b) [for full release of new organism]. The word 'occasions' suggests specific events and occurrences. The reason is obvious, to have on hand the best information about the risks of the organism. The use of the word 'all' requires an attempt at comprehensiveness.

3.25 Section 140(1)(k) provides that countries and organisations may be specified.

3.26 Forms under the 1998 regulations state that if no regulations exist under s140(1)(k) this information need not be given. This with respect appears ultra vires. However, GE Free is not now contesting this issue in terms of adequacy of information.

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[2] Interpretations and Explanations of Key Concepts, Preface, page i
[3] Interpretations and Explanations of Key Concepts, Preface, page 1.1

"Information about the containment system for the organism/s"

3.27 The Act does not define "containment system", but defines containment:

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

3.28 It also defined a containment facility:

> Containment facility means,—
>
> (a) In relation to new organisms (other than genetically modified organisms), a facility registered as a containment facility under the Biosecurity Act 1993:
>
> (b) In relation to genetically modified organisms, a facility which complies with the controls imposed by an approval granted under [any of sections 42, 42A, 42B, or 45]:

3.29 A containment structure is defined as:

> 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.

3.30 For applications for development outside containment and field testing (7074, 7001) the Act requires cleanup of sites to occur. That can include leaving material in the soil:

> Section 45A(3) In subsection (2), destroyed includes leaving genetic elements to break down or become inactive at the site of the development or field test.

3.31 The definition of "containment system" refers to a secure location or secure facility. Locations are obviously a critical matter when considering risk. In considering controls for importing, developing and field testing, ERMA must consider whether to impose controls locating facilities "outside the usual habitat range of the organism". (3rd schedule cl 5(b)(ii)).

3.32 The Methodology Order includes the requirement that, in assessing risk, ERMA must consider "[t]he risk is subject to uncontrollable spread and is likely to extend its effects beyond the immediate location of incidence" (cl 33(c)). That assessment requires knowledge of the place where the incident might occur.

3.33 The detailed application forms provide that for a development outside containment:

> Section Five of Application Form — Proposed containment system and controls
>
> Section 5.1 – Outline of proposed outdoor development site
>
> Attach maps and diagrams of the proposed development site(s) showing the layout and indicate land uses adjacent to the development site (these may be submitted as confidential information if necessary). Clearly indicate the size, location and number of organisms on the site.

3.34 The field test form provides (NO-04):

> Section 4.1 - Information on the field trial design: size, scale and duration of the field test
>
> Attach maps and diagrams of the proposed field test sites and layout and indicate land uses adjacent to field trial site, mark buffer zones and show isolation distances if relevant. Clearly indicate the size, location and number of field test sites.

3.35 The Key Concepts document is unequivocal that location is required in each case for considering the containment system and provides the following reasoning:

> 3.6 Containment (including genetically modified organisms)
>
> Containment may be described as establishing barriers (physical and procedural) to prevent release of the organism to the uncontrolled environment. Containment approvals (see below) include field testing and fermentation of genetically modified organisms. An application for approval for containment <u>will specify the secure location or facility where the organism is to be contained</u>. A secure location or facility is one that is under the supervision of the facility manager; who must be able to manage the security of the organism, and of material and people within the boundaries of the containment zone. If this is not possible, the application should be for release.
>
> …. With respect to specific containment facility performance parameters, MAF and ERMA New Zealand have developed a number of standards (see MAF/ERMA Standards at the front of this document) relating to containment requirements. These standards range from guidelines for fencing for containment of different types of animals to specifications for laboratories.
>
> (underlining added)

3.36 This makes it clear that the location is a separate consideration from general standards of containment. Standards cannot cope with every eventuality on every site. The actual geographical location of a facility provides vital risk information to ERMA, so that it is able to determine, despite any general standards, whether there are particular features of this site which require particular measures to better manage risk, or mean that it should be turned down.

3.37 In addition, the Act requires all persons exercising functions, powers, and duties under it to take into account "the relationship of Maori and their culture and traditions with their ancestral lands, water, sites, waahi tapu, valued flora and fauna, and other taonga" (s6(d)). This requirement is repeated in the Methodology cl 9(c)(iv) and cl 25(2). It will be important for local iwi and hapu to know where a site is of a notified application. If an iwi or hapu submits, that will be important information for ERMA to take into account.

3.38 The need for this precaution is that, as was noted in *Madge*, that field tests would usually take place in release like conditions since field-testing will often precede a full release application. If locations are required for containment, and for development outside containment, then all the more so for full scale field tests.

3.39 Form 4 deals with field tests in containment and ERMA guidance on that form notes (ER-UG-NO-04-3 02/08 p5):

> Level of information to be provided
>
> The level of information and analysis you need to provide for a field test application is considerably more than that required for a development in containment application. This is because there are greater possibilities of adverse effects in field test experiments. Since field tests are required to be contained it is critical that you demonstrate that the organism(s) and any heritable genetic material will be adequately contained.

Identification of the organism

3.40 "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).

3.41 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):

> 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.

3.42 For field tests, the genetic elements do not need to be laid out so precisely because the organism has presumably already been developed under a prior approval. For example, Form 4 for field tests asks:

> 3.3 Provide details on the genetic modifications and processes involved in the development of each of the organism(s) to be tested
>
> Experimental data and information obtained from the development phase of each genetically modified organism should be attached to this application as an Appendix to assist in risk evaluation.

3.43 There are several discussions in ERMA 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)

3.44 The Key Concepts Guide provides this discussion: 3.21.3

> 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 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.

3.45 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 (s27A). Section 27A provides:

> 27A Approvals at any taxonomic classification
>
> (1) An approval referred to in section 27 … (c) [An approval to import any new organism into containment, field test any new organism in containment, develop any new organism in containment] may be granted for a new organism at any taxonomic classification that the Authority thinks fit.
>
> (2) An approval that is granted for a new organism (that is not a genetically modified organism) in a taxonomic classification applies to all the organisms in the taxonomic classification.
>
> (3) An approval that is granted for a genetically modified organism in a taxonomic classification applies only to organisms in the taxonomic classification with the same genetic modification as specified in the approval.
>
> (4) Despite subsections (2) and (3), an approval may exclude any organism or groups of organisms from its scope.

3.46 Taxonomic classification means (s2) "in relation to an organism, means the genus, species, subspecies, infrasubspecies, variety, strain, cultivar, or other appropriate classification that the organism belongs to." Key Concepts explains:

> An approval that is granted for a genetically modified organism in a taxonomic classification applies only to organisms in the taxonomic classification with the same genetic modification as specified in the approval. This means an identical nucleic acid sequence inserted (or deleted or modified) at the same site within the genome as the organism that has been approved.
>
> …. The granting of approvals at "the most appropriate taxonomic classification" allows ERMA New Zealand to consider applications for approval to import or release new organisms at the most appropriate taxonomic level for risk assessment.

3.47 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.

"All possible adverse effects of the GMO on the environment"

3.48 This is not a matter of only assessing the impacts of the host organism, but the GMO, a separate organism. Beyond the requirements in s40, the 1998 regulations and methodology order specify what matters need to be considered and how they are considered.

3.49 The 1998 regulations require information on such matters as:

> 9 Assessment of risks, costs, and benefits
>
> (1) The identification and assessment of risk required in each application must include—
>
> (a) The nature of the adverse effects of the organism; and
>
> (b) The probability of occurrence and the magnitude of each adverse effect; and
>
> (c) Risk assessed as a combination of the magnitude of the adverse effect and the probability of its occurrence; and
>
> (d) Options and proposals for managing the risks identified; and
>
> (e) The uncertainty bounds on the information contained in the assessment, expressed quantitatively where possible, but otherwise by narrative statements.

3.50 Information is also required about any adverse effects on Maori (1998 regulations forms).

3.51 Dr Allen in her affidavit refers to the generic ERMA approval which was the subject of the *Madge* case (para 188). The committee there noted that a lack of specificity in the description of an organism and outdoor containment can

make an assessment of all possible adverse effects difficult to achieve. The committee thought that a 'standard of reasonableness" should be applied.

4. THE TEST FOR SUFFICIENT INFORMATION TO NOTIFY APPLICATIONS

4.1 The decision on whether there is sufficient information to notify under section 53 is a statutory power of decision. This seems to be accepted by all parties. The affidavit of Mr Atapattu notes that public notification of an application does not happen until it has been formally received and "the relevant ERMA staff are satisfied it complies with the statutory requirements" (para 21, and also 24-28). ERMA accepts that compliance with s40 information requirements as to identification and containment are important because "potential adverse effects mostly flow from the biological characteristics of the organism and are mitigated by containment" (Atapattu affidavit para 26).

4.2 The process for dealing with an application is:

(a) ERMA staff may assist applicant with information requirements (Methodology Order cl 2(2)(f)).

(b) Receipt of applications.

(c) Further information is sought under s52.

(d) Decision that the application contains sufficient information to be notified.

(e) Public notice.

(f) Closing date for public submissions.

(g) Section 58 review from outside sources – if ERMA chooses.

(h) Material to submitters at least 10 working days before a hearing.

(i) Hearing.

4.3 In terms of ERMA receiving applications:

(a) There is plenty of scope of ensuring that applicants provide sufficient information prior to notification. ERMA staff are enjoined to assist applicants to determine what information to include in applications Methodology Order clause 2(2)(f) (and did

so in this case). Prior to public notification, there is a process to ask the applicant for further information – s52.

(b) ERMA has to assume the applicant is seeking what is set out in their application unchanged and that they will seek to exercise their full rights under the application ie to the limit of its scope. The legislation does not treat an application as an 'opening bid', nor is ERMA's decision an "in principle" one with full details to be worked out later.

(c) By notifying an application, ERMA is indicating that the outcome sought by the applicant is prima facie a possibility (ie the application is not outside statute).

(d) The Act contemplates a decision on the application even if no submissions are received or whether any submitters appear at any pre hearing meetings or the hearing itself.

4.4 In term of potential submitters:

(a) They likewise have to assume that the full extent of the application is being sought.

(b) Potential submitters therefore, like ERMA, need information to make that assessment and respond.

(c) Submissions are not an expression of interest – they have value as actual evidence to assist decisions on risk (Methodology Order clause 15). And submitters may be from all walks of life – lay through to expert.

(d) Potential submitters have only one entry point into the process, that is, during the public notice period. There is no opportunity for new submitters to come into the process, for example, after a s58 report has been received. Indeed, a s58 report is not even required to be prepared (s58 uses the word "may").

(e) Making a submission provides important rights to participate in the process, but also to exercise a right of appeal to the High Court on a

matter of law. So understanding what an application entails is critical to those rights of participation.

(f) Submitters have limited rights at a hearing. There is no right to cross examination.

4.5 There is a suggestion from the *Madge* case that the ERMA decision as to whether it has sufficient public information to notify an application is made after the decision to send it for external review:

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

4.6 In that case the Court was dealing with a challenge after the Authority had reached its decision and had dealt with submissions on the issue of adequacy of information.

4.7 However, the Court cannot have been suggesting in the first sentence above that the determination of whether the application falls within jurisdiction is made after public notification and after an external review under section 58. Parliament cannot have intended that the Authority notify something for public comment which would be open to legal challenge, so that ERMA could not approve it, no matter what submissions might be received.

4.8 In terms of process, an analogy can be made with resource consents under the Resource Management Act 1991 (the "RMA"). The basic procedural approach is the same, with an application being made (s88), notification (s93ff), submissions received (s96), expert reports on the application may be prepared (s92) possible pre hearing meetings (s99), and a hearing with limited rights (ss100 and 39). In *AFFCO NZ Ltd v Far North District Council (No 2)* [1994] NZRMA 224 (PT) the then Planning Tribunal (now Environment Court), after reflecting on the provisions under the RMA setting out what information was required noted (p14):

> From those provisions we infer that it is intended that the proposed activity the subject of the resource consent application is to be described with sufficient particularity to enable those various functions to be performed. The proposed activity has to be described in detail sufficient to enable the effects of carrying it on to be assessed in the way described by the Fourth Schedule. The description is intended to include whatever information is required for a consent authority to understand its nature and the effects that it would have on the environment. The description is expected to be full enough that a would-be submitter could give reasons for a submission about it and state the general nature of conditions sought. The application needs to have such particulars that the consent authority would need to be able to have regard to the effects of allowing the activity, and to decide what conditions to impose to avoid, remedy or mitigate adverse effects without abdicating from its duty by postponing consideration of details or delegating them officials.

4.9 The court further commented on the detail required:

> … good resource management practice requires that sufficient particulars are given with an application to enable those who might wish to make submissions on it to be able to assess the effects on the environment and on their own interests of the proposed activity. Advisers to consent authorities and would-be submitters should not themselves have to engage in detailed investigations to enable them to assess the effects. It is an applicant's responsibility to provide all the details and information about the proposal that are necessary to enable that to be done. The proposal and the supporting plans and other material deposited for public scrutiny at the consent authority's office should contain sufficient detail for those assessments to be made.

4.10 The court also made this point:

> It is to be remembered that unlike corresponding legislation in England, the Resource Management Act makes no provision for outline approval, or approval in principle, the final permission to follow on subsequent presentation of more detailed plans. Under this Act, a consent authority is expected to make a final decision, and if resource consent is granted, to impose conditions that will enable the grantee to assess their full effect before deciding whether or not to exercise the consent.

4.11 That case concerned a failure to provide details of a waste water treatment and disposal system in connection with an abattoir proposal. Such challenges are common in the Environment Court. A recent example being *Petone Planning Action Group v Hutt City Council v Hutt City Council*, 2 May 2008 W020/08.

4.12 It is submitted that the last observation above is particularly pertinent in this case. While applications to ERMA may be generic, they must contain definite information to determine their scope and possible effects, because the legislation provides a single notification, submission, hearing and approval process at which all issues are dealt with. There is no prior formal ‘shaping’ process involving the public. The application must arrive and be notified with

enough detail for ERMA to contemplate final approval (with or without conditions) even should no further information be provided.

4.13 To the extent that ERMA's approach to the need for adequate information in an application may differ from that, it is submitted that it is in error. Ms Atapattu deposes that a relevant consideration in ERMA's determination of adequate information was "that the Authority can subsequently obtain information about the risks, costs and benefits of proposals from a variety of other sources, including submissions from the public and expert advice from ERMA staff and external consultants" (Atapattu affidavit para 30). Dr Allen, discussing whether the applications address all possible adverse effects, argues that once experts have reviewed the applications, submitters will be sent a copy of their report "and, if present at the hearing, will have the further opportunity to discuss the potential adverse effects identified by the applicant and the project team" (para 195).

4.14 The process under the Act does not contemplate that considerations such as the ability of submitters to attend a hearing, or the provision of expert reports after notification, goes so far as to 'repair' some lack of essential information in a proposal. As noted above, the Act allows a decision to be made on a proposal even if no submissions are received. When deciding that there is sufficient information to notify, ERMA cannot therefore contemplate submissions that are not yet made but might be received and what they might cover (or for that matter evidence in expert reports yet to be commissioned) as a relevant matter.

4.15 In her affidavit, Dr Allen suggests that the public does have sufficient information to make submissions about the field test application "including voicing concerns about the broad nature of the application" (para 163). That suggests that the test for ERMA is whether there is sufficient information to enable a submitter to possibly complain that the application is too broad to be understood. In other words, if it is hard to understand the breadth of the application, that will be a reason for notifying it or at least not a reason for withholding notification. That cannot be a correct approach in law.

4.16 In the *Madge* case the issue of sufficient information for "identification" of GMOs under s40(2)(a) was specifically considered:

> [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 s40(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.

4.17 From the information requirements under the HSNO one can see why the court considered that these matters will "invariably depend on expert assessment". It sets a high bar. But it is submitted that the court cannot have meant that these issues are always and in all circumstances beyond the purview of the court. There is no suggestion in the legislation to that end. It is submitted that applications will be reviewable in limited circumstances where information is so deficient on the face of the application that there can be no expectation that experts (or lay persons) will have information with which to identify with any specificity the GMO and its possible adverse effects. The absence of information must be such that it makes meaningful understanding of the proposal and assessment of risks by experts or the public extremely difficult. The lack of information needs to be obvious and not a matter of expert interpretation.

4.18 How information requirements are interpreted is also influenced by overarching requirements of risk assessment and precaution in the Act (*National Beekeepers' Association of New Zealand v Chief Executive of the Ministry of Agriculture and Forestry* 4/12/07 CA 128/07):

> [21] The HSNO Bill had its genesis in Part 13 of the Resource Management Act 1991 which provided for the establishment of a Hazards Control Commission. In terms of s 345(2) Resource Management Act, this was a body designed to:
>
> [B]alance the benefits which may be obtained from hazardous substances and new organisms against the risks and damage to the environment and to the health, safety and economic, social and cultural wellbeing of people and communities … .
>
> [50] The language in ss 4 and 5 is reminiscent of the language adopted in Part 2 of the Resource Management Act. There is a strong emphasis on the protection of the environment (which is widely defined) and the

> protection of health and safety. The focus is on preventing or managing the adverse effects of hazardous substances and new organisms. The protection function is emphasised in s 7 by the precautionary approach in cases where there is scientific and technical uncertainty.

4.19 It will also be relevant if a lack of information makes other assessments required by the Act impossible. For example the requirements under s44A(2)(b) [alternative methods to achieve research objectives] and (c) [horizontal gene transfer] and the general determination provision, s45, which requires ERMA to consider all the effects of the GMO (s45(1)(a)(ii)).

4.20 AgResearch comments in each of the applications that to comply with the requirements of the HSNO Act, its information must be sufficient for three purposes:

> To enable ERMA to determine what information, if any, ERMA might need to properly assess the application;
>
> To enable ERMA (and submitters) to assess adverse effects and benefits, accepting that ERMA may request and the applicant may supply additional information for this purpose;
>
> If an approval is granted, to provide a reference point so ERMA/MAF might know with certainty what it is that has been granted and therefore be able to ascertain whether the applicant is acting within the scope of the approval granted.

4.21 Items 1 and 2 above suggest that AgResearch, perhaps like ERMA, sees the application process as more of an "application in principle" and places considerable weight on information that might be obtained after submissions have been received. It is submitted that that approach is incorrect, for the reasons noted above. However, it is also submitted that the information gaps are so acute in this case that even the ERMA tests are not satisfied (see further below).

5. THE INFORMATION PROBLEMS IN THE APPLICATIONS

5.1 The *Madge* case decision dealt with a generic application summarised as follows (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.

5.2 These applications helpfully note the extent to which they go beyond the application dealt with in the *Madge* case (8012 pp16-17):

> This application goes beyond GMD02028 in that:
>
> The host organism in GMD02028 was a single species (Bos taurus). In this application the livestock species for which approval are sought are any species within 9 livestock genera; with a range of additional genera required for additional work involving cell lines and small animals.
>
> The source of the donor DNA inserted in GMD02028 is limited to humans, mice, cattle, sheep, deer, or goats. In this application, donor DNA may come from animals, microorganisms, viruses, plants or synthetic sequences and nucleic acids comprising sequences derived from animals, microorganisms, viruses, plants or synthetic sequences and consist of coding, non-coding or regulatory nucleic acids with proven functions
>
> The organism description in GMD02028 permitted the use of only one gene of donor DNA. There is no equivalent limitation in these applications.
>
> Approval is sought for production of biopharmaceuticals and other products with commercial applications for release

5.3 The key concern is that, on their face, vital pieces of information, required by Parliament to allow risk to be assessed, are effectively not given, so that the applications are effectively asking for permission to import, develop and field test;

(a) Livestock;

(b) genetically modified in ways and by methods currently unspecified, some currently known but also any unknown;

(c) for purposes known but currently unspecified and others currently unknown;

(d) at any site in NZ.

5.4 The analysis below uses text from 8012 which is identical in other applications 7074 and 7001 – cross referencing is provided.

Identifying the GMO

5.5 The purposes of the applications make it clear that AgResearch does not want to specify any particular GMO (quotes from 8012):

> Purposes of Application
>
> ….
>
> AgResearch is therefore seeking long term approval to develop genetically modified livestock (cows, buffalo, sheep, pigs, goats, llamas, alpacas, deer, and horses). The livestock will in many cases be maintained in outdoor containment under other approvals (GMD07074 and GMF07001), but stages of development of livestock up to embryo implantation and work with laboratory animal models (and possibly production for release using small animals) will take place in indoor containment under the approval sought in this application.
>
> 8012 p5

5.6 The purposes are broad:

> The purposes for which AgResearch will utilise the approval will depend on the needs of the pastoral sector, commercial opportunities for transgenic livestock-derived products, the applications of transgenic technologies to those needs and consumer attitudes to particular uses of genetic modification. AgResearch believes these purposes will include:
>
> Products with commercial applications: Undertake research and maintain and breed livestock for production of:
>
> therapeutic proteins
>
> proteins for use as diagnostics for human and animal disease
>
> other products derived from livestock with commercial applications
>
> Enhancement of livestock traits: Maintain and breed livestock for research into enhancement of traits of value in livestock including productivity, welfare and sustainability
>
> Animal models of human gene function and physiology: Maintain and breed livestock for use in research as models for human gene function and physiology
>
> Transgenic techniques; gene function: Maintain and breed livestock for research into transgenic techniques and gene function to support the above purposes and, if discoveries of general application are made in the course of such research, for further research into such discoveries.
>
> 8012 p5

5.7 No one modification or series of modifications is specified. Rather, any modification to service any of the above general purposes is requested. The purposes are so general that not even one 'therapeutic protein' development is identified. The categories are so broad that there is actually no limit to the modifications. In particular, item 4 provides, that, should any general matters arise, those may also be researched without further application being made. 8012 pp9-10 provides:

> Transgenic techniques; gene function in livestock
>
> AgResearch is undertaking a broad research programme into transgenic techniques which is intended to minimise the intrinsic risks of the introduced genetic modifications, increase their predictability and overall efficiency (more detail is provided in section 4.2)
>
> The above programmes of work will require AgResearch to further undertake basic research which will be aimed at improving and understanding gene function in the various livestock species used. It is possible that the research will result in unanticipated discoveries relating to gene function and regulation with benefits other than those which the research was intended to produce. Following up unanticipated discoveries is an integral part of the science process and may produce more significant outcomes than the original research. AgResearch may wish to pursue those discoveries even where they do not contribute to the programmes of work for which the research was originally undertaken.

5.8 The applicant is seeking approval for a purpose which includes an unspecified "broad programme of research" and the ability if "unanticipated discoveries" arise, to pursue those without further application. ERMA has no information at this point on the limits of this application other than the livestock genera named.

5.9 It is submitted that it is not relevant that the applications go on to discuss possible immediate topics of research and approaches that might be taken. The breadth of what is sought and whether the application provides the information to assess the risk of that breadth ("all possible adverse effects") is what that Act requires ERMA to focus on.

5.10 As one reads further into the applications, even more uncertainty about what is being covered emerges. The section on identification of the GMOs states: 8012 p20

> Because of the generic nature and duration of the application, it is not possible to identify at the time of the application the techniques which will be used to genetically modify each line of transgenic animals which will be developed if the approval sought is granted. The techniques

> chosen will depend on nature and purpose of the modification and the techniques then available. AgResearch therefore seeks approval to modify the organisms using any technique then available. In most cases these will be proven techniques, but where AgResearch is conducting research to enhance transgenic methodologies it may wish to test novel approaches.

5.11 Thus host organisms may be modified by all currently known methods and methods yet to be developed but currently unknown to the applicant (or ERMA).

5.12 Coming to the particular methods to be used:

> Genetic modification
>
> In the short term, the mechanisms of creating genetically modified animals will be standard internationally approved experimental methods (eg such as chemical transfection; mechanical transfer, nuclear transfer). However, new techniques with advantages for development of GMOs are likely to be developed over time. Indeed, a major focus of AgResearch's transgenic programme in the immediate future is improving techniques used in transgenesis precisely to reduce uncertainties and risk.

5.13 As with the "unanticipated discoveries" above, the applications seeks the ability to use any and all techniques to develop GMOs, including techniques currently unknown to the applicant. It seeks the ability to determine for itself what "internationally approved experimental methods" might mean.

5.14 As to vectors, the application states (8012 p24):

> AgResearch will use proven vectors including but not limited to viral (replication defective) and non-viral vectors, episomal vectors, and artificial chromosomes containing DNA derived from animals, microorganisms, viruses, plants or synthetic sequences and nucleic acids comprising sequences derived from animals, microorganisms, viruses, plants or synthetic sequences. Proven vectors means described in a scientific publication and characterised for its purpose.

5.15 This has the same problems as the above information. The reference to "proven vectors" is a different way of seeking the same unlimited ability to use all known and as yet unknown materials. The definition of "proven vectors" as "described in a scientific publication and characterised for its purpose" means approval is sought for vectors currently unknown to science. The reference to a scientific publication highlights the problem of risk assessment presented by such unlimited scope. It invites ERMA and submitters to speculate on what future science publications might say about vectors yet unassessed. Yet elsewhere ERMA's detailed application forms

make it clear that science publications on matter such as vectors are an important component of risk analysis. (ref)

5.16 This once again asks for delegated risk assessment by the applicant, which will determine if the future science publication spells out a level of risks in the use of the hitherto unknown vector which is acceptable to it. Some limits (see exclusions p32) are acknowledged, but do not remedy the problem of the unlimited scope outside of those exclusions.

5.17 Some examples of possible new approaches are given, but once again, it is not relevant that ERMA might ask further questions at hearing and gain further information. For notification, the issue is whether there is information about the breadth of what is sought so that risk can be assessed. Plainly, if the applicant themselves has no particular idea of what they might be seeking in this regard, neither can ERMA, or submitters.

5.18 Again, it is not relevant that the applications go on to discuss possible immediate focii and approaches or indicative lists of possible modifications (something which Dr Allen's affidavit deals with at length). The fact is that the applicant is seeking, and if granted can rely on, the full scope of the application. ERMA must contemplate the possibility that AgResearch does none of the research set out as examples, but instead pursues an as yet unspecified modification by currently unknown methods. It is on that basis that ERMA and submitters have to consider the application, whether it assesses all possible adverse effects and whether to submit and what evidence to submit.

5.19 The problem is highlighted in Dr Allen's comment in her affidavit that "if the scientific techniques are standard well known techniques, only brief descriptions are necessary. More specific information is required when unusual or uncommon techniques are to be used" (para 95). In this case the full extent of possible techniques are not even described, let alone information provided about them.

5.20 In terms of the field test, the requirements under s40 as to identification of the organisms differ slightly from those for a development because the intention is that the modified organisms has been created in development and its characteristics are known. The requirement is to provide information on "the

genetic modifications of the organisms to be tested", as compared to "details of the biological material to be used, expression of foreign nucleic acid material" for development.

5.21 AgResearch does not provide definite information about what organisms with what characteristics will be tested:

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

5.22 Even adopting AgResearch's tests on sufficient information, ERMA in proceeding to notify has no idea:

(a) *What further information it might need to assess the applications:* It cannot know what "unanticipated discoveries" are, since the applicant themselves does not, nor does it have any information on the "broad programme of research" referred to. If the suggestion is that ERMA knows to ask for details of what is in that "broad programme of research" that must be in error because the public has no information about or ability to respond and treats the application as some form of invitation to discussion (see above).

(b) *To enable ERMA to determine what information, if any, ERMA might need to properly assess the application:* this criteria likewise will not assist with approving "unanticipated discoveries".

(c) *To enable ERMA (and submitters) to assess adverse effects and benefits:* it is simply impossible to assess the full scope of adverse effects that might arise since the application seeks approval for methods, procedures and GMOs not currently known to any expert.

(d) *If an approval is granted, to provide a reference point so that ERMA/MAF might know with certainty what it is that has been granted and therefore be able to ascertain whether the applicant is acting within the scope of the approval granted:* the application has such broad purposes that it would be hard to find any modification of these many species that falls outside them. There is no research to genetically modify these livestock that could reasonably be ruled out on the purposes given.

5.23 AgResearch argues that this information is sufficient because of the low risk and containment proposals:

> AgResearch believes that the information provided in this section sufficiently describes the organism(s) for which approval are sought to meet those purposes. In particular, it is sufficient to enable ERMA to assess the potential adverse effects of the activities for which approval is sought and the efficacy of controls to mitigate those effects, because in all cases:
>
> Developments for which approval is sought would be classified as "low risk" under the HSNO (Low-Risk Genetic Modification) Regulations 2003, except for the use of certain viral vectors used in the modification process. The risks associated with the use of viral vectors are discussed in some detail in assessment of adverse effects in section 5.3A7.
>
> The host organisms which will be held in containment are species whose management is well understood. They will be held in containment facilities built and operated to a standard designed to isolate those organisms from contact with the environment and the public. No genetic modification (or combination of genetic modifications) of these species would result in the organisms having materially greater ability to escape from containment than the unmodified host organism.
>
> The impacts of the genetically modified organisms within the containment facility will be limited in scale, even if they do occur.
>
> The pathways by which adverse effects caused by the genetic modification could occur outside containment are limited in number and are either addressed in the relevant containment standard or can be addressed in controls imposed by the approval itself. AgResearch has endeavoured to identify those pathways and where appropriate has identified relevant controls in the assessment of the risk of adverse events required by each of the applications
>
> There is now extensive experience in transgenic research in the laboratory environment over several decades involving a vast range of host organisms and modifications. When assessing the probability of unforeseen adverse effects of any magnitude occurring, ERMA is entitled to take into account the absence of any significant adverse effects arising from those activities.

5.24 This reasoning is flawed. First, the suggestion that the developments will all be low risk (which suggests knowledge about risk) is contradicted by statements in the application:

(a) High risk viral vectors will be used;

(b) Permission to use viral and other vectors of currently unknown risk is being sought;

(c) Permission to develop 'unanticipated discoveries' likewise of unknown risk, is being sought.

5.25 Second, the emphasis on containment conflates 2 pieces of information which Parliament specifically and separately requires to enable risk assessment to occur, information about the containment system, and information identifying the organism. AgResearch is in effect inviting ERMA to rewrite the Act such

that the provision of a standardised containment system for 80 plus identified species of livestock can remove any requirement to identify the GMOs and their specific modifications.

5.26 With no parameters other than the genus of 'livestock' defined, essentially the argument of the application reduces to an argument about livestock being large animals which are easily confined:

> The host organisms which will be held in containment are species whose management is well understood. They will be held in containment facilities built and operated to a standard designed to isolate those organisms from contact with the environment and the public. No genetic modification (or combination of genetic modifications) of these species would result in the organisms having materially greater ability to escape from containment than the unmodified host organism.

5.27 But that tells us no more than that the host organisms will be a cow, sheep, goat etc. Parliament has demanded much more than that to make a risk assessment. The applications themselves admit risk pathways to adverse effects which don't rely on cows actually escaping, such as mixing with non-GMOs, leaving genetic elements in the soil etc (refer Ms Bleakley 2nd affidavit para 13).

5.28 The lack of information in these critical areas means that AgResearch's identification of the organism essentially goes no further than "host animal" plus "unspecified and unlimited genetic modification." Here for example is the unique description provided for GMO cattle: 8012 p37

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

5.29 It may be reasonable to seek approval for novel techniques or organisms, which are specified in the application, about which little may currently be known, provided that the uncertainties are spelled out in the application. But it goes too far to seek approval for any possible future organisms and techniques, whose existence is currently unknown. That is seeking a delegation of authority. It also leaves all parties (even the applicant) without any rational means to assess the risks of the proposal.

5.30 Dr Allen tries to explain away this problem by arguing (paras 146-148) that genus level identification in part fulfils the requirement to identify the

organism. She argues that "the commonly farmed animals are readily identifiable with known characteristics and information on these organisms can be readily found." It is submitted that this is simply restating that the application goes no further than "host animal" plus "unspecified and unlimited genetic modification."

5.31 Dr Allen follows this by noting that if there is "uncertainty about the ability to handle or contain certain species" controls can be imposed (para 149). Species at higher risk of escape could be excluded (p150.2). This is an admission that basic information, even about the physical capabilities of the species covered by the application (let alone modifications which might be made), is currently unavailable to assess the proposal.

Field test location

5.32 The applicant has not specified any sites where activities will take place. The applications state: 8012 p10:

> Location of activities
>
> AgResearch currently operates a research facility at Ruakura, near Hamilton, which has a MAF approved indoor and animal outdoor containment facility facilities in which all organisms involved in genetic modification research are located. In the short term the research will be undertaken only at this site. However, the existing outdoor containment facility is on leased land and is close to residential areas which restricts the ability to expand capacity and means it is unlikely to be the long term site of all research activities. If commercial therapeutic protein production commences, it is likely to be at a separate facility from that which carries out the initial research phases of the program.
>
> For these reasons AgResearch is seeking a non-specific site approval. Other suitable sites around New Zealand may therefore be used at some future time to fulfil the requirements needed for the production of commercial volumes of selected therapeutic proteins or to allow research phases to continue.
>
> (underlining added)
>
> …. We acknowledge that the lack of specificity relating to the site raises an issue for ERMA as to whether it can properly assess effects of the activities for which we are seeking approval without knowing where the activities are carried out. AgResearch believes that ERMA can assess the effects on the basis that:
>
> All activities will be undertaken within a containment facility operated in accordance with standards and procedures approved by MAF and ERMA with a very low or negligible risk of physical or biological effects outside the facility (see discussion in section 5.1). Ethical, social and economic effects identified in section 5.2 are not site specific.

> AgResearch notified 150 neighbours around Ruakura at the time the existing outdoor containment facility was built and sought their views. Apart from one phone call seeking clarification of the exact site, none of the neighbours raised any concerns. AgResearch has been openly operating an outdoor containment facility at Ruakura for 8 years in proximity to a residential area in a major city, and has gone through 3 application processes. In that time we are not aware of any local individuals or community agencies raising concerns that activities had adverse effects of any kind which ERMA is required to consider under the HSNO Act or Methodology Order (other than one of the groups who we consult with for Ngati Wairere). We understand PPL who operated a transgenic sheep facility had similar experiences.
>
> Any activities are likely to occur in containment at one of AgResearch's existing research campuses. AgResearch will establish consultative processes with the tangata whenua at any new site we establish (see discussion in section 6.2D) and community liaison groups to ensure local communities have access to information about the transgenic programme.

5.33 The application extensively discusses standards for the containment. ERMA's view that standards for containment and knowledge of sites are separate matters has been noted above. ERMA asked for further information about sites but was advised:

> As explained in the applications the risks are generic in nature and are unlikely to change from site to site except for cultural risk to Maori for which national consultation was undertaken. AgResearch considers that consultation with individuals within rural communities (potential neighbours) was not required as potential community or social impacts are already well understood. Undertaking site specific consultation would not in our view, have provided any further elaboration of these concerns.

5.34 The contention that site risks are "unlikely" to change from site to site seems to acknowledge that they can differ from site to site. That acknowledgement is particularly important since the range of possible sites is any location in New Zealand Over such a range, 'unlikely' may become 'likely' in some places or areas.

5.35 In seeking any location in New Zealand there is no information to assess this parameter. Not knowing what the field test will be about also makes assessment of this matter extremely difficult.

5.36 Potential submitters may have important practical information about proposed sites. For example, sites in gullies might incur more damage during flood events and runoff paths might take material in unexpected directions. Steep or broken country might make fence lines less secure than on flat sites. Spots prone to excessive dry spells and wind might raise issues about airborne material. Local people are well placed to comment on such issues, as

can ERMA, once it is aware of sites. A general standard cannot cover all eventualities.

5.37 Nor does ERMA or Maori have any ability to assess s6(d) issues. Dr Hutchings affidavit discusses the problems with a proposal which does not state whether it will locate within a particular iwi or hapu area, and where in that area. The sensitivity of sites varies with the strength of ancestral links with them.

5.38 The affidavits of Mr Hale and Mr Slattery do not dispute that that AgResearch would have the final word on location. Rather, they express the belief that consultation will result in a satisfactory outcome. This does not address the legal issue of an effectively delegated authority to determine where sites are located and whether s6(d) issues have been satisfied.

5.39 Both stress that national consultation has been undertaken. However, the Executive Summary of that consultation notes concerns about the breadth of the application (Appendix VI 7074 p4):

> There were requests for wider disclosure of the draft application and for greater specificity around the potential application sites and species.

5.40 The adequacy of that consultation can be judged from these comments in the report (Appendix VI 7074 p18):

> I am unhappy that the draft is not available now. It is unfair to the iwi and hapu. The application itself would clarify things. You are asking Maori for their opinion but haven't provided the specific application to comment on.
>
> (Malibu Hamilton, Hamilton Hui)
>
> A big issue in the consultation process is lack of prior information before the application is due. We're just ordinary people we need to be in this process.
>
> I don't expect that this is the final part of the process. I believe in this process.
>
> (Emma Gibbs-Smith, Whangarei Hui)
>
> Why is this consultation happening now without a copy of the application being available for us to see?
>
> (Z Vallings, Whangarei Hui)

5.41 AgResearch argues that consultation will resolve any issues. But the application will already have given AgResearch the legal authority to locate

anywhere, with no ability for an iwi (or for that matter, say local farmers), to invoke the ERMA process to put forward information and evidence for the authority to determine if a site or sites raises particular issues under the Act. Assessment of this risk will be placed in the hands of AgResearch.

5.42 This is particularly concerning in this case because AgResearch is requesting not only no limit to the location of sites, but no limit to the number, or their size (7001 p37 refers to maximum numbers being determined by the size of the containment facility).

5.43 Ms Allen argues in her affidavit that in 'clearly identifying' that sites are unspecified (an oxymoron), the public has "sufficient information to make submissions about the application (including voicing concerns about the unspecified location of containment facilities …. (para 135 underlining added). This misunderstands the process. Submissions are not meant to be a matter of 'voicing concerns' but responding in a specific and focussed manner to specific information to assist ERMA in its risk management role (see also para 162 where Dr Allen suggests that the public might also in submissions "voice concerns" about the broad nature of the application).

Field test purpose

5.44 AgResearch has also declined to provide any information on what the field tests will actually do. As noted above, subsections 40(2)(b)(ii)-(iv) requires the purposes of the field testing to be disclosed, as well as the genetic modifications to be tested and the nature and method of the field trials and the experimental procedures to be used.

5.45 AgResearch has provided this information: 7001 p30

> This application is for a generic approval (i.e. approval for any field test of organisms complying with the organism description for the purposes set out in this application) of unlimited duration. It is therefore not possible at the time of application to specify all the details of each field test which may be carried on under this approval (including the effects tested, the location or duration).

5.46 The remainder of this section of the application discusses containment standards. There is no specification of any field test.

5.47 Dr Allen argues that the applicant has "chosen to intertwine this information with the information about the containment system rather than give it separately. It appears that this has been done because of the simple nature of the proposed field testing (ie, the keeping of the GMOS within an enclosed paddock)" (para 127). This misreads the application. It simply states that none of the requirements of 40(2)(b)(ii)-(iv) can be spelt out because AgResearch does not currently know what GMOs will in fact be created, nor therefore what field tests it will undertake.

5.48 Similarly, Professor Atkinson argues in his affidavit that this detail is not important because "[t]he research projects or field tests will involve testing organisms is to establish the level of expression of target proteins, stability of inheritance of the target genes and animal performance" (para 5.2) That information is not in the application., and, even if true, certainly not available to submitters to comment on. Nor do we know if that is all that will be tested.

5.49 The paucity of basic information on which to found any submissions or assessment is illustrated by Dr Allen's tentative summary on the likely effects of field testing (para 192):

> In the absence of specific information on the "effects" that could be tested during the proposed field tests and the experimental procedures to be used may be as simple as keeping the organisms in the field and observing them. The possibility of conducting more specific tests on effects of organisms is mentioned but with no certainty that this will occur.

5.50 The fact that Dr Allen as an expert has to resort to such supposition, succinctly demonstrates the problem with the lack of information in this case.

5.51 To give a simple example of why this information might be important. ERMA might want, for certain GMOs of high risk, to limit the number of tests and/or number of animals involved at one facility to manage the risk of horizontal gene transfer. Or specify that a site is not to be used for certain tests because of potential flooding and soil transport issues. This horizontal gene transfer risk is noted in the table of possible effects in the application for containment (and reproduced in Ms Bleakley's 2nd affidavit para 13). Submitters cannot even begin to deal with these issues because they have no information about what GMOs might be created, with what risks, in what numbers and how and where and how they might be tested.

All possible adverse effects of the organism on the environment

5.52 In the absence of identification of what GMOs will be created, it is not possible to make an assessment of "all possible adverse effects of the organism on the environment." A series of extremely generic tables are provided which could be applied to almost any GMO proposal involving mammals. In terms of field testing, Dr Allen's problems with determining what effects there will be in the absence of any definite information about field tests is noted above. Dr Allen in her affidavit suggests that subsequent expert reports, attendance of submitters at the hearing and brainstorming may expand further on these matters (para 194-5). The problems with that approach in terms of what the Act required and the hearing process have been noted above.

Problems for s44A analysis

5.53 The lack of information on developments outside containment and field tests means that there is no information to inform the consideration of alternatives required under s44A. That requirement is discussed in Key Concepts (pp3.2.1-2):

> The first matter that must be identified is the research objective. In the first instance this will be provided by the applicant and should be reasonably well linked to the purpose statement for the application. In other words, it is not acceptable for the research objective to be quite different from the purpose statement. As it does for other information, ERMA New Zealand will evaluate this with particular attention paid to the rationale for selecting that purpose, particularly by considering the overall context of the application.

5.54 In this case the applicant is simply unable to specify the research objective, because the applications do specify any such objectives. Accordingly, information which Parliament requires to enable ERMA to consider s44A is absent.

5.55 Providing details of research objectives at a later stage would be asking ERMA to delegate its decision making power under this provision. The application for importation (8012) actually notes a number of possible GMO projects that currently take place without GMOs being used – indicating that

the consideration of alternatives would be an important issue, were AgResearch to actually specify any field tests (8012 p8).[4]

5.56 In addition, the consultation with Maori threw up concerns about alternative methods (7074 Appendix VI p13 "Many hui participants asked about alternative methods including illness prevention as well as methods to manufacture the proteins sought.")

5.57 Separately, 44A(2)(a) requires the Authority to set a mandatory control requiring the removal or destruction of heritable material at the end of the development or field test.

5.58 The information gaps prevent ERMA or potential submitters from assessing the potential for horizontal gene transfer ("HGT") in field tests. Section 44A(2)(c) provides:

> In deciding whether to approve or decline an application, the Authority must take into account— ….
>
> (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.

5.59 Genetic elements are defined as:

> genetic element, in relation to a new organism, means—
>
> (a) heritable material; and
>
> (b) any genes, nucleic acids, or other molecules from the organism that can, without human intervention, replicate in a biological system and transfer a character or trait to another organism or to subsequent generations of the organism.

5.60 Key Concepts explains the reasons for including this provision:

> 3.17 Genetic elements - effects from
>
> …. Section 44A(2)(c) is considered to apply to horizontal gene transfer (HGT) as opposed to vertical gene transfer which is addressed in section 45A(2)(a). Applicants will be expected to consider and address in their application the likelihood of HGT and the effects that may arise from it. In other words the impact of the amendment is to make the occurrence and consequence of HGT a matter that must be explicitly considered, irrespective of the likelihood of the occurrence of HGT. Any effects that may arise from HGT will then be considered in the normal course of the consideration process.

[4] Examples of traits targeted by conventional selection and biotechnological research in the recent past are: Reproductive efficiency (increasing live birth lambs per ewe, Muscling (increasing bulk of high value cuts of meat), Tenderness (increasing value of meat)

(underlining added)

5.61 HGT "is the transfer of genetic material from one organism to another that is outside the context of parent to offspring reproduction. It has been demonstrated to occur widely in natural bacterial populations." (P3.19)

5.62 Because there is no limit to the possible developments that will be undertaken, and no field tests are described, ERMA and potential submitters have no information to assess this possibility. Pages 34-37 of the field test application (7001) discuss movement of materials within sites, between sites and even overseas. But without knowledge of the site locations and GMOs that might be developed, the number of sites, or even the numbers of animals at each site (7001 p37 refers to maximum numbers being determined by the size of the containment facility), basic information is missing to make the risk assessment required.

6. CONCLUSION

6.1 An indication of how many unknowns there are in these applications is in this reported request by AgResearch at a meeting with ERMA staff prior to notification (Bleakley 2nd affidavit para 7):

> Requested clarification regarding whether the risks could be assessed based on characteristics of the organisms rather than the method used to develop the organism and questioned what would happen if, in the future, some new, more risky, method was invented that hadn't been assessed for the application.

6.2 ERMA staff is recorded as responding that they would propose "a performance based control [sic] cover these eventualities." That the applications cover this eventuality is not denied by Professor Atkinson who has provided an affidavit for AgResearch. He comments that 'more risky" should be seen as a relative term in a low risk context. He continues "In my opinion, the experimentation and outcomes described remain low risk". With respect, without knowing what possible modifications, experimentation and outcomes might be associated with a new, more risky method, yet to be invented, but covered by these applications, how can he possibly know?

6.3 The practical impact of the inadequacy of information in this case is that ERMA has over 1200 individual submissions before it complaining that there

is no way of understanding the possibilities under this proposal so as to make sensible comment on it. Maori have also made this complaint. The fear, as Dr Wills points out in his affidavit, is that in the absence of information, submissions must necessarily be generic, but that they will then be criticised by ERMA for being such (Without irony, Mr Atapattu comments that ERMA does not have any power to consider generic comments on genetic engineering beyond the scope of the applications it is considering - para 90).

6.4 Mr Slattery argues that most submissions objecting to the proposal were pro forma (para 15). However, he does not contest the number raising a concern about the adequacy of information provided. He points to 2 submissions which he suggests are examples of submitters in objection able to deal substantively with the applications, however:

(a) Ms Dommisse's submission and conclusion are extremely general. She nevertheless recommends that farmers be advised of locations of any testing.

(b) The Sustainability Council submission opens with the heading "Failure to meet HSNO Section 40(2) Tests." It criticizes a 'driftnet approach to the Act and applications that "leave ERMA and submitters with the invidious task for sorting through the tangle of proposed activities described at bird's eye level."

6.5 There is undoubtedly the potential for submitters, whatever decision the Authority makes, to appeal on a matter of law to the High Court – namely that the Authority has acted outside of jurisdiction because the application was deficient. However, there is no certainty that any such appeal would be made. A more fundamental objection is that a creature of statute ought not to embark on an exercise out of jurisdiction on the basis it might be cleared up later.

6.6 A declaration is sought that the applications are deficient in the respects outlined above and that the applications be withdrawn from the process and referred back to ERMA and the applicant to fulfil the statutory requirements.

TH Bennion / IS Spurdle

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