IN THE COURT OF APPEAL OF NEW ZEALAND

CA380/2009
[2010] NZCA 89

BETWEEN	AGRESEARCH LIMITED Appellant
AND	G E FREE NZ IN FOOD AND THE ENVIRONMENT INCORPORATED First Respondent
AND	ENVIRONMENTAL RISK MANAGEMENT AUTHORITY Second Respondent

Hearing: 26 January 2010

Court: Chambers, O'Regan and Arnold JJ

Counsel: J B M Smith and S A Mataga for Appellant
D M Salmon and T H Bennion for First Respondent
P J Radich and L Van Dam for Second Respondent

Judgment: 23 March 2010 at 4 pm

JUDGMENT OF THE COURT

A The appeal is allowed.

B The orders made in the High Court are quashed.

C We make no award of costs.

REASONS OF THE COURT

(Given by O'Regan J)

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Introduction

[1] This is an appeal against a decision of Clifford J,[1] in which he upheld an application by the first respondent (G E Free) for judicial review. He found that the second respondent (ERMA) had erred in law in receiving four applications by the appellant (AgResearch) under s 40 of the Hazardous Substances and New Organisms Act 1996 (the HSNO Act) and commencing the process of determining those applications. Those applications related to proposals by AgResearch to import new organisms and to develop and field test them in containment.

[2] Clifford J found that the applications did not comply with the requirements of s 40(2) and other applicable requirements, and were, in essence, too generic to enable ERMA to undertake the risk assessment (balancing of beneficial effects against adverse effects) that it is required to undertake under s 45 of the HSNO Act.

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1 *G E Free NZ in Food & The Environment Inc v Environmental Risk Management Authority* HC Wellington CIV 2008-485-2370, 5 June 2009.

He set aside ERMA's decision to accept the applications as valid applications under s 40 of the HSNO Act and directed ERMA to take no further steps towards hearing and assessing them.

[3] AgResearch challenges the High Court decision. ERMA took an active role in the appeal and also challenged the High Court decision.

The issues

[4] It is common ground that the applications made by AgResearch were expressed in broad and generic terms. That raises an issue as to whether the applications meet the specific requirements for applications under s 40, as specified in s 40(2), and in regulations made under the HSNO Act and guidelines published by ERMA itself (we will refer to these as the "statutory requirements"). We will discuss that issue in some depth, but ultimately we do not see its resolution as determinative of the appeal.

[5] G E Free says that it is clear that the applications are too generic and are therefore non-compliant. Its counsel, Mr Salmon, said the generic nature of the applications was such that, if ERMA approved them, that would involve an effective delegation of ERMA's decision-making role to AgResearch. AgResearch and ERMA deny this and, more broadly, refute the suggestion that the applications are too generic to meet the statutory requirements.

[6] AgResearch and ERMA also contend that the judicial review proceedings were premature. They argue that because of the technical and scientific nature of the applications, a determination as to whether they comply with the statutory requirements involves scientific judgments which ERMA cannot be expected to make at the outset of its process. They say ERMA should be allowed to continue its consideration of the applications: if it concludes that they do not comply with the statutory requirements, it can dismiss them. The key issue is, therefore, whether ERMA is required to make an assessment as to compliance prior to accepting an application, or whether it is entitled to accept the application and undertake its

statutory assessment of it before reaching a concluded view whether it complies with the statutory requirements.

[7] An alternative argument put forward by AgResearch and ERMA is that ERMA's acceptance of the applications does not amount to a "decision" at all. They argue that, as no statutory power of decision has been invoked, there is nothing to which a judicial review application can apply. On the approach we take to the case, it is not necessary for us to engage with that argument. We will deal with points raised on appeal on the assumption that ERMA's acceptance of the applications and commencement of its consideration of them is a "decision", without making a definitive ruling on the point.

Did the applications comply with the statutory requirements?

AgResearch's applications

[8] The applications made by AgResearch to which the application for judicial review related are described in some detail in the judgment under appeal.[2] There was no challenge to the Judge's description and we will not repeat it: reference should be made to the judgment under appeal if further detail than that in the summary which follows is required.

[9] Clifford J summarised the applications as follows:

> [51] AgResearch applied:
>
> (a) to import into containment new genetically modified organisms comprising specified livestock, laboratory animals and other organisms (the Import Application – GMC07012);
>
> (b) to further develop (i.e. genetically modify) in a containment structure those specified livestock, laboratory animals and other organisms (the Indoor Development Application – GMD08012);
>
> (c) to further develop (i.e. genetically modify) in outdoor containment those specified livestock – but not the

[2] At [51] – [84].

laboratory animals or other organisms (the Outdoor Development Application – GMD07074); and

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

[10] For ease of reference we will refer to the applications using the names given to them above.

[11] The organisms involved in the import application give an indication of the breadth of the applications. They are described in the following table:

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

Cavia	Guinea pig	Animals, animal cells, embryos, sperm, ova
Other organisms:		
Chlorocebus	Monkey	Animal cells
Homo sapiens	Human	Animal cells (excluding gametes and embryonic stem cells)
Escherichia coli (non-pathogenic laboratory strains only)		Bacterium
Saccharomyces, Pichia (non-pathogenic laboratory strains only)		Fungus

[12] AgResearch made no secret of its intention to arm itself with very broad consents allowing it a considerable degree of freedom in its future activities involving genetic modification. In its application summary, it described the applications as follows:

> AgResearch's intention in making the suite of applications is that AgResearch has all possible approvals needed under the HSNO Act for research, breeding and production using livestock in containment. This will ensure that AgResearch has the flexibility to:
>
> - Undertake research or commercial production with transgenic livestock lines which AgResearch has developed itself or with lines developed by other parties and imported.
>
> - Undertake development and maintain livestock in both indoor containment and outdoor containment. For example transgenic goats are provided for in both the indoor and outdoor applications as it is possible that commercial herds will be required to be kept in-doors to meet pharmaceutical regulatory requirements but research herds may be kept in outdoor containment.
>
> - Undertake activities in outdoor containment regardless of whether they are developments or field tests. The boundaries of the field test definition have not been fully tested. However, AgResearch expects field tests may occur if AgResearch is evaluating the effects of livestock in anticipation of a future release approval or if AgResearch is undertaking comparative trials of the effects of transgenic and conventional animals. With both approvals in place, both AgResearch and ERMA can be assured that whatever the boundaries, the activity will be approved under one approval or the other.
>
> The approval sought under this application will also authorise AgResearch to import small animals, cell-lines and microorganisms that support the livestock activities. Cell lines from livestock and small animals and from humans and monkeys will be used for evaluation of DNA construct and experimental strategies. *E. Coli* and yeast will be used for DNA construct

> development. Rats, mice, hamsters, guinea pigs, rabbits, possums will be used as research models for all livestock activities.

[13] The applications were not limited to any specific geographical location, and were also sought for an unlimited duration.

[14] Clifford J concluded as follows in relation to the breadth of the applications:

> [60] The Application Summary makes it clear, therefore, that the Applications, if approved, would allow AgResearch first to import into containment specified organism types of the specified livestock, laboratory animals and other organisms, already genetically modified in ways not previously present in New Zealand. Once imported, AgResearch could further genetically modify those organisms whilst in indoor containment. Finally, AgResearch could further genetically modify in outdoor containment, and field test, the specified livestock.
>
> [61] AgResearch could use any technique available, now or in the future, to effect such genetic modification and could do so using genetic material from the specified livestock, small animals, humans and monkeys, *E. Coli* and yeast organisms as specified in the Applications. Each of those approvals could be implemented at Ruakura, or at yet to be located facilities.

The statutory context

[15] AgResearch required approval from ERMA for the activities covered by its applications because s 25(1) prohibits the importing, developing, field testing or releasing of any "new organism" otherwise than in accordance with an approval issued under the HSNO Act, unless the transitional provisions in parts 11 — 16 of the HSNO Act apply (they do not apply in this case). A "new organism" is defined in s 2A as including a genetically modified organism.

[16] The two provisions at the heart of this appeal are s 40, which deals with applications relating to proposals involving new organisms, and s 45, which deals with the determination of such applications.

[17] Section 40(1) requires that an application for approval must be made to ERMA by any person who intends to import into containment any new organism or develop or field test any new organism in containment. Section 40(2) sets out the requirements for any such application as follows:

40 Application for containment approval for new organisms

...

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

(a) for the development of a genetically modified organism,—

(i) the identification of the organism; and

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

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

(iv) the expression of foreign [nucleic acid material]; and

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

(b) for field testing of a genetically modified organism,—

(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.

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

[19] Section 55 provides for the possibility that an intended applicant will provide information to ERMA before making an application. This can be in the form of a

draft application, so ERMA's officers' views on its compliance with the statutory requirements can be obtained. We are told this informal process was adopted in this case before the applications were finalised.

[20] Section 45 deals with ERMA's determination of any application for approval under s 40. It relevantly provides:

> **45 Determination of application**
>
> (1) After considering any application for approval made under section 40 of this Act, the Authority (if the application is not approved under section 42 or section 42A or section 42B) may, in its discretion,—
>
> (a) approve the application if—
>
> (i) the application is for 1 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 (for applications made under section 40(1)(b)) or the matters in section 44 (for applications made under section 40(1)(a) or (c)), the beneficial effects of having the organism in containment outweigh the adverse effects of the organism and any inseparable organism; and
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> (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; and
>
> (b) may include controls that provide for any other matters in order to give effect to the purpose of this Act.
>
> ...

[21] Two points about s 45 need to be highlighted. The first is that the primary test to be applied by ERMA is a balancing of beneficial effects of having an organism in containment against the adverse effects of the organism and any inseparable organism: s 45(1)(a)(ii). The second is that s 45(2) states that an approval under s 45 must include controls to provide for matters specified in

Schedule 3 to the HSNO Act and may include controls that provide for any other matters in order to give effect to the purposes of the HSNO Act.

[22] AgResearch and ERMA argued before us that this power to impose controls means that the breadth of the AgResearch application does not need to be a matter of concern, because ERMA will be able to impose controls limiting the scope of the application and the activities authorised by it to address any concerns. Mr Salmon accepted that was so. But he said the problem from the point of view of submitters was that they would not have prior notice of those controls and therefore were limited in the scope of their submissions in opposition to commenting on the generic risks of genetic modification rather than on the specific risks of modification of particular organisms in particular host animals. He said it was also possible that potential submitters would decide not to participate in the process, based on the application itself, when they may well have had something to offer in relation to the proposal for which approval is eventually given.

[23] Three other aspects of ERMA's statutory processes are important.

[24] Section 53 deals with public notification of applications. In the present case the field test application was subject to the compulsory public notification regime in s 53(1). In relation to the others, public notification was not mandatory, but under s 53(2) ERMA may notify other applications if it considers there will be significant public interest. ERMA did so in relation to the other three AgResearch applications, so all were publicly notified.

[25] Section 52 allows ERMA to give notice to an applicant requiring the applicant to supply further information in relation to its application where ERMA "considers that the applicant is able to provide further relevant information". If the applicant fails to comply with such a request within a year, the application lapses. ERMA did exercise this power in the present case, but it was common ground that the material provided by AgResearch in response to the notice essentially repeated material contained in the applications. ERMA reached the view that AgResearch could not provide further relevant information and did not pursue the matter further.

[26] Section 58(1)(a) provides that ERMA may commission a report or seek advice from any person on any matters raised in relation to an application, including a review of any information provided by the applicant. This allows ERMA to obtain an independent assessment of material provided to it by an applicant, whether in the application itself or in material provided in response to a s 52 request.

Section 40(2) requirements

[27] Mr Salmon said that the AgResearch applications failed to comply in a number of areas. It is not necessary for us to address that argument in detail. Instead we will consider two examples of alleged non-compliance with the requirements specified in s 40(2).

Identification of organism

[28] Section 40(2)(a)(i) and (b)(i) apply to the Indoor Development Application, the Outdoor Development Application and the Field Test Application. They require the "identification of the organism". "Organism" is defined in s 2. Mr Salmon argued that the identification of organisms to be developed and/or field tested at a genus level rather than by reference to specific species in a list which includes most genera of livestock commercially found in New Zealand did not meet the statutory requirement. He said this provided little more information than that the species of the specified genera will be genetically modified. No detail was given as to the characteristics, biological nature or hazards intrinsic to the relevant organisms for the simple reason that this information could not be provided given the generic nature of the applications.

[29] He made a similar criticism of the information given to satisfy the requirement of s 40(2)(a)(ii) (description of the project and experimental procedures to be used), which relates to both the Indoor Development Application and the Outdoor Development Application.

[30] Rather than specify particular processes, the two applications state that, 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". Both applications then state that AgResearch is seeking approval to modify/develop organisms "using any technique available".

[31] Clifford J had before him affidavits from ERMA's New Organisms Application Manager, Mr Atapattu and its Senior Environmental Risk Adviser, Dr Allen. The latter expressed the view that the genus level identification of the host organisms in the applications did "in part" fit the criteria of s 40(2)(a)(i) of the HSNO Act "as the biological nature of the nature and degree or type of hazard intrinsic to host organisms within a genus have been identified by classification into a particular genus". She qualified that view by adding: "However, this is subject to consideration of the genetic modification of the host organism".

[32] Clifford J considered that the generic nature of the applications meant that ERMA could not carry out the risk assessment it must undertake under the HSNO Act.[3] He accepted, citing the *MAdGE* case,[4] that generic applications may be made (and approved)[5] but noted that the applications themselves acknowledged that they went beyond the application under consideration in the *MAdGE* case to a considerable extent.[6] He accepted that ERMA was able to undertake some risk assessment on the basis of the applications as filed but only at a generic level, rather than in relation to specific genetically modified organisms as he considered was required under the HSNO Act.[7] He said the HSNO Act did not provide for the establishment of a national protocol, as AgResearch appeared to be seeking.[8]

[33] Counsel for AgResearch, Mr Smith, argued that the organisms to which the applications relate were "identified" if not specified. He said there were many

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3 At [139]

4 *Mothers Against Genetic Engineering Incorporated v The Minister for the Environment* HC Auckland CIV 2003-404-673 7 July 2003, Potter J ("the *MAdGE* case").

5 At [69].

6 At [130].

7 At [140].

8 At [141].

millions of organisms covered by the generic wording, but they could, in theory, be listed by reference to that generic wording. He said the organisms were identified "albeit within extremely broad parameters instead of one by one".

[34] Mr Radich relied on the evidence of Dr Allen that the applications did "identify" the organisms sufficiently for ERMA to accept them and commence its statutory process of evaluating them.

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

Were judicial review proceedings premature?

[36] Mr Salmon argued that it was incumbent on ERMA to ensure that applications met the statutory requirements before embarking on its assessment. He said that the failure to do this made it difficult for ERMA to carry out its risk assessment but, more importantly, made it difficult if not impossible for those who had responded to the public notification to participate fully in the process. That was because, as noted earlier, the lack of specificity reduced them to commenting on genetic modification generically, rather than on the risks and benefits of genetic modification of particular organisms by particular techniques, as the HSNO Act contemplated. He also argued that there may be members of the public who did not elect to participate in the process because they could not recognise the potential impact of the applications due to their generic nature.

Other statutes

[37] The HSNO Act itself is silent on what ERMA is to do when it receives an application which may not comply with the specific requirements of s 40(2) and the regulations and guidelines. Counsel focused their arguments on the HSNO Act. Before turning to those arguments, we will compare the relevant provisions of the HSNO Act with those in other Acts relating to other statutory consent processes. That exercise reveals that other statutes address the issue which is now before us explicitly, in contrast to the lack of any specific provision in the HSNO Act. The statutes we considered were the Commerce Act 1986, the Resource Management Act 1991 and the Medicines Act 1981.

Commerce Act

[38] Section 60 of the Commerce Act deals with applications for authorisation of restrictive trade practices. Section 60(1) requires that applications "shall be made in the prescribed form [and] shall contain such particulars as may be specified in the form".

[39] Section 60(4) expressly deals with the situation where an application does not comply with those requirements. It provides:

> (4) On receipt of an application that does not comply with sub-section (1), the Commission may, at its discretion, either –
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> (a) accept the application and [register it and publicly notify it]; or
>
> (b) return the application to the person by or on whose behalf it was made; or
>
> (c) decline to register the application until it complies with sub-section (1).

[40] Like ERMA, the Commission has power to require that further information be provided to it in the course of its consideration of an application for authorisation.

[41] It is instructive that this regime appears to contemplate that the process of considering an application for authorisation will begin with an inadequate application which may be supplemented later by information provided to the Commission in the course of its inquiries. Essentially, that is the same as what ERMA proposes in this case. On the other hand, it gives the decision-making body a specific statutory power to refuse to accept a non-complying application. That is what Mr Salmon said ERMA should have done here, despite the lack of any similar provision in the HSNO Act.

Resource Management Act

[42] Section 88(2) of the Resource Management Act requires that applications for resource consent must be made "in the prescribed form and manner" and include an assessment of environmental effects in such detail as corresponds with the scale and significance of the effects which the activity may have on the environment. If the application does not do so, the local authority may determine that the application is incomplete and return the application, with written reasons to the applicant.[9] Such a decision by a local authority is subject to the right of objection under s 357 and, if the objection is unsuccessful, there is a right of appeal to the Environment Court under s 358.[10]

[43] This regime broadly mirrors the regime contended for by G E Free in the present case. But it is notable that, whereas the Resource Management Act specifically provides for such a regime, the HSNO Act is completely silent.

Medicines Act

[44] The Medicines Act regulates products and providers of therapeutic products, including medicines. Licences are required for the manufacture, wholesaling or retail sale of medicines in New Zealand.

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9 Section 88(3).
10 Section 88(5).

[45] Applications for licences are made under s 50, which requires that they be submitted to the Director-General of Health or his or her delegate. Applications are required to "contain or be accompanied by such particulars, information, documents, samples and other material as may be prescribed". Under s 50(5), if the person authorised to receive the application "is satisfied that an application complies with the requirements of this section and of any regulations made under this Act that are applicable to the application", the person must refer the application to the Licensing Authority (the Licensing Authority is the Director-General of Health or his or her delegate).

[46] Section 51 deals with the consideration of an application that has been referred to the Licensing Authority. One of the matters in respect of which the Licensing Authority must be satisfied before issuing the licence is "that the requirements of s 50 have been complied with".[11]

[47] It is apparent that this regime contemplates that there will be an initial decision by the recipient of the application as to its compliance, and that once the recipient is satisfied of compliance the matter will then be referred to the Licensing Authority, who will also be required to assure himself or herself of that compliance. This process is also similar to that advocated for by G E Free in this case, though in the Medicines Act it appears that different officials may be required to address the issue of compliance under s 50 and, subsequently, under s 51. Again, it is notable that the HSNO Act does not have any provision similar to those in ss 50 and 51 of the Medicines Act. Every other statutory application process that we have examined clearly provides a right to reject an application for not adhering to the stipulated form.

This case

[48] The absence of any specific provisions of the kind described above in the HSNO Act means the intention of Parliament as to the steps required to be taken by ERMA on receipt of an application is unclear. That means the issue must be decided

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[11] Medicines Act 1981, s 51(1)(a).

by reference to other indicators in the HSNO Act and in accordance with the purpose of that legislation.

[49] Mr Smith argued that it was not possible for ERMA, let alone the High Court on review, to evaluate alleged aspects of non-compliance with the statutory requirements prior to the commencement of ERMA's consideration of the intended application. Such an evaluation could be done only with the benefit of scientific expertise which ERMA has, but which the Court does not, and only in the course of ERMA's consideration of the application when the necessary scientific expertise can be applied. He said that the statutory requirements had to be read in light of other provisions in the HSNO Act, including in particular:

(a) Section 45(1)(a)(ii), which requires ERMA to undertake a risk/reward assessment of the proposal to which the application relates. Mr Smith argued that the purpose of the statutory requirements was to facilitate that assessment.

(b) The definition of "identification" in s 2, which envisages that the person undertaking the statutory functions in relation to identifying an organism will apply scientific knowledge. He said the same applied to other defined terms such as "new organism" and "genetically modified organism".

(c) Section 16, which requires that members of ERMA must have "knowledge and experience in matters likely to come before [ERMA]".

(d) Section 45(2), which, as noted earlier, empowers ERMA to impose controls.

(e) Section 52, which gives ERMA the power to seek further information.

(f) Section 58, which gives ERMA the power to commission reports.

[50] Mr Smith argued that all of these factors supported AgResearch's contention that the HSNO Act does not envisage either ERMA or a Court making a decision on the acceptability of an application for approval prior to the substantive assessment process to be undertaken by ERMA.

[51] Mr Smith argued that, in the absence of any provision in the HSNO Act dealing with non-compliance with the statutory requirements, a nuanced approach was required. He cited in support of that proposition the often-quoted judgment of Lord Hailsham in *London & Clydesdale Estate Ltd v Aberdeen District Council.*[12] In the present case, he argued, it would be sensible and in keeping with the HSNO Act's purpose to respond to any non-compliance with the statutory requirements (if these could be identified with certainty at such an early stage of the ERMA process) by allowing ERMA the latitude to continue hearing the applications, using its statutory powers under s 52 and s 58 if required. He said the finding of the High Court Judge[13] that it was difficult to see how ERMA could carry out the s 45 risk assessment given the generic nature of the applications was contrary to the view expressed by Dr Allen and did not allow for the potential exercise of ERMA's statutory powers to seek further information during the process of consideration of the applications. Even if the current position was that the applications were non-compliant, the appropriate step for the Court on review was to decline relief and allow ERMA to complete its task.

[52] Mr Smith also criticised the Judge's finding[14] that the breadth and generic nature of the applications meant that the information required for effective public input had not been made available. He argued that any problems caused by the generic nature of the applications could be a matter of submission during the course of the ERMA process and pointed out that public notification was not even required in relation to three out of four of the applications.

[53] ERMA supported the position taken by AgResearch. Its counsel, Mr Radich,

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12 *London & Clydesdale Estate Ltd v Aberdeen District Council* [1979] 3 All ER 876 (HL) at 883.
13 At [139].
14 At [145].

said that ERMA did not believe it had a power or right to refuse to receive an application that did not comply strictly with the requirements of s 40(2) (or those of the regulations or guidelines). He said that ERMA saw its function on receipt of an application as simply that of verifying that the applicant has made a reasonable attempt at completing the application. He questioned the utility of ERMA being required to undertake a full assessment involving use of scientific expertise to determine whether an application complied with all requirements prior to embarking on its formal process of assessment as required by s 45.

[54] Like Mr Smith, Mr Radich relied on the powers of ERMA to call for further information under s 52 and to commission reports under s 58 as supporting his submission. He emphasised the difficulties which ERMA would face if it was were required to assess each application under s 40 at the outset and to refuse to accept the application on the basis that it provided insufficient information. He said the assessment as to whether an applicant had sufficiently identified an organism, described the project and experimental procedures, detailed the biological material to be used and identified the possible adverse effects was one requiring complex scientific and technical evaluations. It would be burdensome for ERMA, and ERMA would need guidance from the Court as to how the supposed power was to be exercised. He expressed the view that adherence to the strict terms of s 40 was "virtually impossible".

Our approach

[55] We do not discount the importance to organisations such as G E Free, which wishes to take an active role in proceedings before ERMA, of having a clear understanding of the proposal to which they are to respond. But we do not accept Mr Salmon's proposition that ERMA has a statutory obligation to vet each s 40(1) application and to reject it if it is not satisfied that the application complies strictly with the statutory requirements. That is not to say that ERMA is obliged to accept everything which an applicant claims is a s 40(1) application, regardless of any obvious deficiencies.

[56] Ultimately ERMA has to satisfy itself, prior to making its decision under s 45, that the application before it (as modified or clarified in the course of ERMA's consideration) is an application falling within the scope of s 40 and to which ERMA's approval can be given. We think this last point meets Mr Salmon's concern that if ERMA is not required to vet applications at the outset and reject those that do not comply with the statutory requirements, ERMA may undertake the s 45 analysis of AgResearch's proposal and reach a positive conclusion without ever satisfying itself that the application is one that is capable of being approved. 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.

[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 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.

[59] We regard the decision of ERMA officials to register the AgResearch applications as essentially mechanical. We do not consider that decision to be of sufficient moment to be appropriately the focus of orders in judicial review proceedings. As we see it, the acceptance of an application for processing does not involve any kind of seal of approval by ERMA and does not preclude ERMA from ultimately dismissing the application because its generic nature does not make it capable of approval or, perhaps more likely, its generic nature means that the quantification of risks and benefits is so uncertain as to leave ERMA unsatisfied that the latter outweigh the former.

[60] There is no doubt that the generic nature of the application in this case provides particular challenges to ERMA. But we do not think it would be helpful for this Court to attempt any guidance at this stage of the ERMA process. All we need to say for present purposes is that, in order to give approval to the applications, ERMA will have to be satisfied that they are applications to which approval can be given under the powers provided to ERMA under s 45 (that is, they are, in fact applications within s 40(1)) and that the threshold for approval under the s 45 test is met.

Result

[61] We disagree, therefore, with the approach of the High Court Judge. In our view, the essentially mechanical decision made by ERMA to accept and register the applications should be allowed to stand. ERMA should continue its process of assessment of the applications. We therefore allow the appeal and quash the orders made in the High Court setting aside ERMA's decision to accept the applications and directing ERMA to take no further steps towards hearing and asserting the applications.

Costs

[62] AgResearch and ERMA accepted that there was a public interest aspect to the litigation. Both claimed costs, but on a reduced basis. In our view, the issues raised by the appeal are issues of significance and G E Free's position was responsibly

advanced. Indeed, it succeeded in the High Court. In those circumstances, we make no award of costs. If costs are sought in the High Court, application should be made to that Court.

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