

**IN THE HIGH COURT
WELLINGTON REGISTRY**

.....

UNDER THE

Hazardous Substances and New Organisms
Act 1996

BETWEEN

**GE FREE NZ IN FOOD AND
ENVIRONMENT INCORPORATED** an
incorporated society whose registered
office is at Shop 4, Doreen Doolan Mall,
Britannia Street, Petone

Appellant

AND

**ENVIRONMENTAL RISK
MANAGEMENT AUTHORITY**, an
authority established pursuant to section 14
of the Act located at Level 1 BP House, 20
Customhouse Quay, Wellington

Decision-maker

AND

AGRESEARCH LIMITED, a Crown
Research Institute with its Corporate
Office being at 5th Floor, Tower Block,
Ruakura Research Centre, East Street,
Hamilton

Applicant

NOTICE OF APPEAL

DATED THIS 11TH MAY 2010

Solicitor: Tom Bennion
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Tom Bennion

NOTICE OF APPEAL

Dated this 7th day of May 2010

TAKE NOTICE that the Appellant hereby appeals against the decision of the Environmental Risk Management Authority (“the Authority”) dated 13 April 2010 in respect of Application ERMA 200223

1. BACKGROUND

- 1.1 The Applicant applied to the Authority under section 40(1)(b) of the Hazardous Substances and New Organisms Act 1996 (“the Act”) to develop in containment genetically modified goats, sheep and cattle to produce human therapeutic proteins, or with altered levels of endogenous proteins for the study of gene function, milk composition and disease (“the application”).
- 1.2 The Appellant made written submissions and on the application and appeared and made oral submissions before a committee of the Authority which considered the application.
- 1.3 The committee of the Authority considered the application under the Act and under the Hazardous Substances and New Organisms Act Methodology Order 1998 (“the Methodology Order”) and on the 13th of April 2010 the Authority issued a decision granting the application, with controls (“the decision”).

2. ERRORS OF LAW ALLEGED

Deficient application

- 2.1 The Authority erred in law in processing the application because such applications must include under section 40:
 - (a) For the development of a genetically modified organism:
 - (i) The identification of the organism; and
 - (iii) The details of the biological material to be used;
 - (iv) The expression of foreign nucleic acid material;
 - (v) All the possible adverse effects of the organism on the environment.

2.2 In addition, the Authority is required to keep a register of all applications made to it available for public inspection which provides, inter alia, “s20(1)(b) a sufficient description of the substance or organism to uniquely identify that substance or organism.”

2.3 In addition, section 44A requires that:

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

(a) any adverse effects of developing or field testing the organism on—

(i) human health and safety; and

(ii) the environment, in particular ecosystems and their constituent parts; and

(b) any alternative method of achieving the research objective that has fewer adverse effects on the matters referred to in paragraph (a) than the development or field test; and

(c) any effects resulting from the transfer of any genetic elements to other organisms in or around the site of the development or field test.

2.4 Instead of meeting these requirements, the application:

- (a) Provided an Appendix of over 700 pages (Appendix II) that listed over 8,000 E. coli strains, as well as hundreds of mammalian cell lines, genetic material donors, proteins/genes to be expressed or down regulated, plasmid/vectors, selection markers and reporter systems, protein tags and fusion partners and additional vector elements to be used.
- (b) Listed types of proteins/genes to be investigated without naming specific protein/genes, meaning that the scope of potential proteins that could be investigated was very large.
- (c) Did not provide a sufficient description of any genetically modified organism to uniquely identify it.
- (d) Did not provide a sufficient description of any genetically modified organism to know whether section 44A was satisfied or not, including in particular section 44A(b).

Use of controls provision to amend application

2.5 The Authority erred in law in proceeding on the basis that the provision for controls under section 45(2)(b) means that “controls may be imposed to define and limit the scope of the organisms to be considered, and these need to be set before the application is assessed under section 45” (underlining added) and defining the organisms to be considered in Appendix 1 of its decision before assessing them under section 45 (Decision paragraphs 4.1.2 and 4.3.8 and Appendix 1).

Deficient assessment of the amended application

2.6 Assuming that the Authority was entitled to amend and then assess the application which it had so amended, the Authority erred in law in assessing the organisms which it described in Appendix 1 of its decision, since they still failed to fulfil the requirements of section 40, namely, the identification of the organisms, the details of the biological material to be used and the expression of the foreign nucleic acid material and the other matters under paragraph 2.4 above.

Failure to consult with iwi

2.7 The Authority erred in law in accepting that the applicant was not required to consult with iwi on this application on the basis that previous applications much broader than this application had been the subject of previous national consultation (Decision paragraph 6.2.27).

3. THE GROUNDS OF THE APPELLANT’S APPEAL

3.1 The Appellant was a person who made submissions to the Environmental Risk Management Authority on application ERMA 200223.

3.2 The Environmental Risk Management Authority made the errors of law specified above in its decision of 13 April 2010 on application ERMA 200223.

3.3 The errors of law specified above affected materially the said decision.

4. RELIEF SOUGHT

4.1 The Appellant seeks the following relief:

- (a) An order quashing Environmental Risk Management Authority’s decision.

- (b) An order remitting application ERMA200223 back to the Environmental Risk Management Authority for further consideration and determination.
- (c) Costs.
- (d) Such further or other orders as the Court considers the case requires.

4.2 **THIS** Notice of Appeal is made in reliance on section 126 of the Hazardous Substances and New Organisms Act 1996 and Part XX of the High Court Rules 1985 as amended.

DATED at Wellington this 11th day of May 2010



TH Bennion

Solicitor for the Appellant

TO: The Registrar, High Court, Wellington

AND TO: The Chief Executive, Environmental Risk Management Authority

AND TO: Company Office of AgResearch Limited

THIS notice of appeal is filed by **THOMAS HUGH BENNION**, solicitor for the Appellant. The address for service of the Appellant is at the offices of Bennion Law, Room 512, Harbour City Tower, 29 Brandon Street Wellington.

Documents for service on the above-named Plaintiff may be left at that address for service or may be:

- Posted to the solicitor at PO Box 25433 Panama Street Wellington; or
- Transmitted to the solicitor by facsimile to 04 4735751.