

# ENVIRONMENTAL RISK MANAGEMENT AUTHORITY DECISION

Amended under s67A 27 March 2002, 18 May 2006 30 August 2007, 12 November 2008 and 11 March 2010

Application Code	GMF98009	Original Decision	23 May 2001
Hearing Date	25 August 1999		
Initially considered by	Special Committee of the Authority appointed under <i>section 19(2)(b)</i> of the Hazardous Substances and New Organisms Act 1996		
Further considered* by	A further Special Committee of the Authority appointed under section 19(2)(b) of the Hazardous Substances and New Organisms Act 1996		

\* Further consideration directed by the High Court in its decision dated 2 May 2001

## APPLICATION DETAILS

Application Code	GMF98009
Application Category	Field Test in Containment any New Organism
Applicant	New Zealand Pastoral Agricultural Research Institute Ltd (AgResearch)
Purpose	To field test, in Waikato, genetically modified cattle with extra bovine genes, the insertion of the human myelin basic protein gene, and the deletion of the bovine $\beta$ -lactoglobulin gene. Genes will be expressed in the milk of the cattle.
Date Application Received	11 December 1998

## SUMMARY OF DECISION

The following organism is **approved** for field testing, **with controls**, having been further considered in accordance with the relevant provisions of the Hazardous Substances and New Organisms (HSNO) Act 1996, of the HSNO (Methodology) Order 1998, and the High Court order of 2 May 2001:

*Bos taurus* (cattle): Construct: Myelin Basic Protein (MBP) cattle (insertion of sequence coding for human myelin basic protein); Phenotype: expression of the human myelin basic protein in the milk of genetically modified cattle.

This decision follows the decision of the Authority on two of the three constructs for which approval was sought under application GMF98009.

The following two constructs were approved by the Authority on 18 November 1999:

1. *Bos taurus* (cattle): Construct: casein<sup>plus</sup> (insertion of additional cattle milk casein protein genes); Phenotype: enhanced expression of casein in the milk of genetically modified cattle to increase the casein content of milk relative to that of total solids.

2. *Bos taurus* (cattle): Construct: BLG<sup>minus</sup> (disruption of the cattle  $\beta$ -lactoglobulin locus, to inactivate the gene); Phenotype: reduced  $\beta$ -lactoglobulin content of milk of genetically modified cattle relative to total solids.

This decision should be read in conjunction with the decision on the two constructs approved in November 1999.

# APPLICATION PROCESS

## Initial processing

The application was formally received on **11 December 1998** and verified on 12 March 1999, following a number of additional information requests.

The application was publicly notified on **17 March 1999** in *The Dominion*, *The New Zealand Herald*, *The Press* and *The Otago Daily Times*.

Public submissions closed on **30 April 1999**. Thirty submissions were received. A list of submitters is attached as **Annex 1** to this decision.

The documents available for the evaluation and review of the application by ERMA New Zealand included: the application (including supporting documentation and confidential information provided), public submissions, submissions and comment from other government agencies [including the Ministry of Agriculture and Forestry (MAF) and the Ministry of Health], and an external scientific review (of the application and submissions) undertaken by Professor Hugh Blair.

In accordance with *section 19(2)(b)* of the Hazardous Substances and New Organisms Act 1996, the Authority appointed a Special Committee to determine the application. The Committee comprised members of the Authority, including: Professor Barry Scott (Chairman), Helen Hughes, Bill Falconer, Dr Oliver Sutherland, Professor Colin Mantell one external member, Leatrice Welsh (expert in Māori culture and traditions).

## Hearing

A public hearing was held on 25 August 1999 in Wellington, with submissions received from the parties listed below. In addition the Committee invited members of Te Kōtuku Whenua, of Ngāti Wairere, the hapū that has mana whenua over the land on which the field test is to be undertaken, to attend the hearing to provide further information on the risks to the relationship of Māori and their culture and traditions with taonga.

## Presentations

Presentations were made to the Special Committee by the following parties:

For the applicant:

1. Dr Keith Steele Chief Executive, AgResearch
2. Dr Phil L'Huillier Scientist, AgResearch
3. Professor Pat Sullivan Massey University

For Ngāti Wairere:

1. Meto Hopa Kaumātua (Ngāti Wairere)
2. Maree Pene Director, Te Kōtuku Whenua (Ngāti Wairere)
3. Jackie Amohanga Researcher, Te Kōtuku Whenua (Ngāti Paretekawa, Kaputui)

4. Maria Henry                      Te Kōtuku Whenua (Ngāti Wairere)
5. Malibu Hamilton                Researcher, Te Kōtuku Whenua (Ngāti Te Wehe)

For ERMA New Zealand:

1. Elizabeth Beale      Project Leader, ERMA New Zealand

For Ngā Kaihautū Tikanga Taiao<sup>1</sup>:

1. Gerrard Albert                      Ngā Kaihautū Tikanga Taiao

Submitters:

1. Angeline Greensill                Private
2. Martin Dawson                      **Witness** to Angeline Greensill
3. Reuben Ashford                      Ngā Pukana, **Witness** to Angeline Greensill
4. Susan Redward                      Federated Farmers of NZ Ltd
5. Charlie Pedersen                      **Witness** to Susan Redward
6. Wendy McGuinness                Private
7. Claire Bleakley                      Private
8. Dr Kevin Marshall                      New Zealand Dairy Board
9. Robert Lind                              New Zealand Food & Beverages Exporter's Council Inc
10. Robert Welch                        NZ Biotechnologies Ltd
11. Noel K Wierzbicki                      Private
12. Berylla Berylla                      Private
13. Oraina Jones                        Private
14. Alan Fricker                              **Witness** to Berylla Berylla
15. David Foote                              Private
16. Pauline Blaikie                        **Witness** to Noel K Wierzbicki

Additional information sought and considered by the Committee included:

1. Further information on the benefits of the application (a part of this material was identified by the applicant as *commercially sensitive* and not released for comment).
2. Information on the impact of spiritual/cultural affront to Māori health (to the social and cultural wellbeing of people and communities).

The information detailed above was forwarded to *parties*<sup>2</sup> to the application for comment. The Committee considered comments received.

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<sup>1</sup> Ngā Kaihautū Tikanga Taiao has been formally established under *clause 42* of the First Schedule to the Hazardous Substances and New Organisms Act 1996, as a Māori advisory committee, to advise the Authority on how to take account of issues of concern to Māori (particularly in relation to *sections 5(b) 6(d) and 8* of the Act).

<sup>2</sup> Parties: Including submitters, the applicant and relevant Government agencies from whom comment on the application was received.

## Further Adjournment of the Consideration

Following the completion of its consideration of the two constructs approved on 18 November 1999, the Committee decided to seek further information in respect of the MBP construct, and adjourn its consideration until the information was received.

Information was sought principally from representatives of Ngāti Wairere, the Tainui hapū having mana whenua over the land on which the field test is to be undertaken, to assist the Committee in forming a view on the *Risks to the Relationship of Māori and their Culture and Traditions with Taonga*, specifically on the relationship of Ngāti Wairere with their taonga.

Information was sought on any measures that could be taken that may ameliorate the concerns expressed by representatives of Ngāti Wairere with respect to the genetic modification for expression of MBP. The specification for the information sought is attached as **Annex 2**. In order to provide all the relevant information to the Committee, the request was made to Te Kōtuku Whenua Consultants and Nga Mana Tōpu O Kirikiriroa, as representatives of Ngāti Wairere, the Waikato Raupatu Lands Trust (Tainui), and the applicant, AgResearch.

## Completion of Initial consideration and Appeal on Points of Law

The initial consideration of the application was completed and the decision released on 21 July 2000. An appeal on points of law under s126 of the HSNO Act was subsequently lodged with the High Court in Wellington on 21 August 2000.

The High Court on 2 May 2001 set aside the Authority's decision of 21 July 2000 and directed the Authority "to consider and decide the application applying so far as relevant the Methodology Order and stating the methodology criteria upon which it relies".

## Further consideration

On Thursday 10 May 2001 the Authority established a special committee to conduct the further consideration. The Authority delegated to the Committee all necessary powers to determine the application in accordance with the order of the High Court pursuant to s.19(2) of the Act. The Special Committee consisted of three Members of the Authority being Dr Oliver Sutherland (Chairperson), Dr Helen Hughes and Professor Colin Mantell, and one external member being Ms Leatrice Welsh, an expert in Māori culture and traditions. All of the Committee members were involved in the initial consideration. They are therefore familiar with the application and all the relevant information, including the submissions made both in writing and at the public hearing on 25 August 1999, and the further information made available later that year and in 2000.

References to the "Committee" in the remainder of this decision mean the Special Committee appointed to undertake the consideration.

The Committee has seen and taken advice on the following matters raised in recent correspondence, on behalf of submitters:

- The wish of some persons to make further submissions to the Committee, particularly on the application of the Methodology;
- The view that new information has arisen since the initial decision which should be taken into account by the Committee.

The Committee has received advice on the application of the Methodology and decided that it is unlikely to be assisted by, and does not wish to hear further from, any persons on the matters subject to consideration. It is advised by ERMA New Zealand staff that there is no significant new information bearing on this application which has come to light since July 2000 and which it ought properly to take into account. Matters raised in recent correspondence are not new to the Committee.

The Committee has accordingly determined that it would conduct its consideration on the basis of the information already available on the application, and that it could see no call for any further submissions or for a further public hearing. The consideration was concluded on that basis.

## THE APPLICATION

The application is for approval to produce and field test in containment, cattle containing a genetic construct comprising a sequence that codes for a human protein, myelin basic protein (MBP), in order to evaluate the milk produced. Cows containing this construct are expected to produce human MBP in their milk.

The development of genetically modified embryos, by AgResearch, has been approved under the HSNO Act by AgResearch's Ruakura Institutional Biological Safety Committee (IBSC) under delegated authority from the Environmental Risk Management Authority (the Authority).

The application and additional information provided by the applicant identifies a range of regulatory and marker sequences that may be utilised in constructs to produce cattle of the phenotype identified. The controls on this approval specify that, any further constructs and genetically modified embryos developed, using different combinations of regulatory sequences must be approved by AgResearch's Ruakura IBSC prior to production, and subsequent field testing, of resulting cattle. The **Schedule** to this decision defines the scope of any further constructs to be utilised for the production and field testing of cattle under this approval.

The production and field testing of cattle from these embryos will be undertaken at AgResearch's Ruakura Research Centre (RRC). The applicant intends to produce one herd of up to thirty genetically modified cattle. The number of cattle involved in the field test (including BLG<sup>minus</sup> and casein<sup>plus</sup> cattle, previously approved), including genetically modified and conventional cattle, will not exceed the capacity of the containment facility<sup>3</sup>, as approved under the MAF Biosecurity Authority/ERMA New Zealand Animal Health and Welfare Standard 154.03.06 *Containment Standard for Field Testing of Farm Animals*, and/or any requirements of the relevant Animal Ethics Committee (AEC), and should at all times be the minimum number of animals required to obtain statistically significant results. In any event, the total number of cattle involved in the field test shall not at any one time exceed 200 animals.

In essence, this application covers an extension of research already undertaken on the development of the genetically modified embryos.

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<sup>3</sup> The *containment facility* refers to the area where the genetically modified cattle are to be maintained, and that is registered by MAF under the Biosecurity Act 1993.

# OUTLINE OF AND BASIS FOR THE FURTHER CONSIDERATION

## Outline

The Committee's consideration of the applications is discussed below under the following headings:

1. The identification of the significant risks, costs and benefits of the organism
2. The adequacy of the proposed containment regime and its ability to mitigate risks, including:

The ability of the organism or any heritable material to escape from containment, including:

- i. breach of containment following deliberate action
- ii. containment of bulls
- iii. containment of semen and ova.

Other containment issues including:

- i. disposal of genetically modified cattle
- ii. disposal of surrogate mothers
- iii. disposal of milk.

3. The assessment of the significant risks (magnitude and probability of adverse effects) and other adverse effects of the organism, including:
  - i. animal welfare issues
  - ii. risks to the biological and physical environment
  - iii. risks to public health
  - iv. long term unanticipated effects
4. Assessment of the risks to the relationship of Māori and their culture and traditions with their ancestral lands, water, sites, waahi tapu, valued flora and fauna, and other taonga; risks to their economic, social and cultural wellbeing; and the application of the principles of the Treaty of Waitangi.
5. The assessment of the significant benefits and costs associated with the application..
6. Establishment of risk characteristics and thus the appropriate approach to risk.
7. The overall evaluation and weighing up of risks, costs and benefits.
8. Decision.

## **Statutory Basis for Further Consideration ie Application Of The Relevant Legislative and Regulatory Criteria**

The application was lodged pursuant to *section 40* of the Hazardous Substances and New Organisms (HSNO) Act 1996, and determined in accordance with *section 45*, the additional matters contained in *sections 37* and *44*, and the matters set out in Part II of the Act.

Consideration of the application was also carried out in accordance with the relevant provisions of the Hazardous Substances and New Organisms (Methodology) Order 1998 (the Methodology). In this respect relevant provisions of the Methodology were taken account of in each instance where that was appropriate.

## **Information Base for the Further Consideration**

The Chief Executive of the Authority engaged the services of a scientific expert, Professor Hugh Blair (in accordance with clause 17 of the Methodology) for the initial consideration to assist in the provision and review of information.

The information available for the further consideration comprised all of that information available when the matter was first considered and then decided in July 2000 including that in the application, that contained in the Evaluation and Review Report prepared by the staff of the Authority, that contained in reports from the Māori advisory committee, Ngā Kaihautū Tikanga Taiao, further information from the applicant, the report from Professor Blair and information and evidence contained in submissions which was considered by the Committee to be relevant (in accordance with clause 15 of the Methodology). It also included additional information obtained under section 58 of the Act (in accordance with clause 23 of the Methodology) including information from both the applicant and Ngāti Wairere.

## **The Sequence of Steps in the Consideration**

In accordance with clause 24 of the Methodology, the approach adopted by the Committee was to look sequentially at identification, assessment and evaluation of risks and of costs and benefits. Management techniques were considered in relation to the identified risks (clauses 24 and 12 of the Methodology refer), and those risks identified as significant were assessed (clause 12). Costs and benefits were assessed in accordance with clause 13 of the Methodology.

Risk characteristics were then established, in accordance with clause 33 of the Methodology.

Finally the combined impact of risks, costs and benefits was evaluated, in accordance with clause 34 of the Methodology and taking account of the risk characteristics established in accordance with clause 33 of the Methodology.

## THE IDENTIFICATION OF THE SIGNIFICANT RISKS, COSTS AND BENEFITS OF THE ORGANISM

Significant risks identified for assessment and evaluation were as follows, following clauses 9 and 10 of the Methodology which incorporate sections 5,6,8 and 44 of the Act.

- Risks to the welfare of the cattle (in accordance with clause 9(c)(i).)
- Risks to organisms in the soil environment within the containment facility, from the transfer of transgenic material from animal waste and the disposal on site of milk and carcasses (in accordance with clause 9(a), (b)(i), (c)(iii), (c)(iv), clause 10(b), 10(d).)
- Risks to water, notably ground water, arising from transgenic material from animal waste and the disposal on site of milk and carcasses (in accordance with clause 9(a), (b)(i), (c)(ii), (c)(iii), and (c)(iv), clause 10(b).)
- Risks arising from the mating of genetically modified and non-genetically modified cattle. (in accordance with Clause 9(c)(i), (c)(ii).)
- Risks of a long term, unanticipated nature (potentially in accordance with Clause 9 or 10)
- Risks to public health arising from the consumption of milk or meat or products containing these, derived from genetically modified cattle (in accordance with Clause 9(b)(i), 9(c)(iii), 9(c)(iv); Clause 10(c).)
- Risks to Māori (in accordance with clauses 9 (b)(i), (c)(iii), (c)(iv), clause 10(c);
  - spiritual beliefs, through interference with the mauri and whakapapa of valued species,
  - degradation of tūpuna land,
  - metaphysical effects on health,
  - risks to the integrity of the Treaty of Waitangi.

Significant benefits identified for assessment and evaluation were as follow:

- Benefits of scientific knowledge arising from the carrying out of the research (in accordance with clause 9(b)(i); 9(c)(v).)

## ADEQUACY OF THE PROPOSED CONTAINMENT REGIME

The Authority considered the adequacy of containment in accordance with s 45(1)(a)(iii) of the Act, and the magnitude and probability of the risks, costs and benefits at the same time and in an integrated fashion. This is because the former interacts with the latter and this is recognised in clause 12(d) of the Methodology and in s45(1)(a)(ii) of the Act. For convenience in setting out the decision the adequacy of containment is however discussed first.

The Committee's consideration of the adequacy of the proposed containment regime focused on the ability of the organism to escape from containment (s 44(b))

### **The ability of the organism to escape from containment**

In considering the ability of the organism to escape from containment, the Committee considered *inter alia*, the following specific points:

- i. breach of containment following deliberate action
- ii. containment of bulls
- iii. containment of semen and ova.

The Committee is satisfied, subject to the controls imposed in this decision, that the containment regime can adequately contain cattle as a part of this field test. The controls require cattle to be produced and maintained in a registered containment facility, operated, constructed and managed in accordance with the MAF Biosecurity Authority/ERMA New Zealand Animal Health and Welfare Standard 154.03.06: *Containment Standard for Field Testing of Farm Animals*, and to comply with other controls as specified.

Additional measures have been put in place over and above the requirements of the Standard to further reduce the probability of any escape of cattle from the containment facility. These include: the erection of two 2 metre perimeter fences (instead of the single 2 metre fence required in the relevant Standard), and the installation of a system to electronically monitor the perimeter fencing in order to promptly detect any interference or break in the fence.

Under this regime, the Committee concludes that the probability of an escape from the facility is very low.

Subsequent to the Authority's approval of the first two components of this application, AgResearch has advised that the containment facility maintaining the cattle has been extended from 4 ha to 45ha. The extended facility has been approved by MAF under the MAF Biosecurity Authority/ERMA New Zealand Standard 154.03.06, and the Committee considers that it provides equivalent containment to the previous 4 ha facility.

#### **i. Breach of containment following deliberate action**

The Committee was satisfied that the construction, operation and management of the containment facility minimises the possibility of any deliberate action or sabotage and minimises the possibility of any such action resulting in a breach of containment, taking into account the nature of the fencing, electronic monitoring, and the location of the containment facility within the Ruakura Research Centre (RRC).

In addition, identification measures in place for genetically modified cattle, including ear tags and sub-cutaneous microchips, would facilitate rapid identification of any animals should a breach of containment occur.

## **ii. Containment of bulls**

Concerns were raised at the hearing regarding the ability of the applicant to contain bulls within the containment facility.

Taking into account the requirements of the standard and the proposed containment regime, the Committee concluded that the probability of bulls escaping from containment is very low. In addition, the location of the containment facility within the AgResearch RRC will provide for close supervision of the small number of bulls to be maintained.

## **iii. Containment of semen and ova**

For the purposes of publication and verification of any research results, the applicant may retain semen and/or ova from genetically modified cattle following the conclusion of the field test. Any semen or ova retained shall be held in accordance with the provisions of approvals to develop the genetically modified cattle (specifically embryos) and the control conditions to which these approvals are subject.

## **Other Containment Issues**

Consideration was given to the following aspects of containing the organisms and any biological material:

- i. disposal of genetically modified cattle
- ii. disposal of surrogate mothers
- iii. disposal of milk.

### **i. Disposal of genetically modified cattle**

All genetically modified cattle, aborted fetuses and non-genetically modified offspring from the cattle shall be disposed of by burial on-site<sup>4</sup>, in a manner which minimises leaching to defined aquifers. Furthermore, controls to which this decision is subject require that the applicant engage in ongoing consultation with Ngāti Wairere (who have manuhenua over the land) over disposal of biological material derived from genetically modified cattle.

### **ii. Disposal of surrogate cows**

The applicant requested that any controls imposed by the Committee regarding the disposal of cattle no longer required for the field test allow for the sale of conventional cattle that have failed to become pregnant following embryo transfer.

Consideration was given to whether the sale of conventional cattle that have failed to become pregnant or which have given birth to genetically modified calves would pose any threat to the

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<sup>4</sup> On-site refers to any place on AgResearch property within the Ruakura Research Centre.

environment or public health. The key issues included the possibility of conventional cows following embryo transfer or the birth of a genetically modified calf containing any genetically modified cells and the possibility of any failure to detect a pregnancy.

Following embryo transfer if the animal becomes pregnant but aborts the pregnancy at an early stage embryonic foetal red cells can enter the maternal circulation and will circulate for the life of the red blood cell. The life cycle of the foetal red blood cell may be up to 50 days.

The applicant proposes to undertake three pregnancy scans (by ultrasonography) in order to verify pregnancy in conventional cows. Following three negative pregnancy tests the possibility of any cow being pregnant is considered to be very low.

The Committee has therefore accepted that conventional surrogate cows that fail to become pregnant may be sold or otherwise disposed of off-site. However the release of such animals from the containment facility is contingent on the animal producing three negative pregnancy scans performed at approximately 28, 35 and 50 days post embryo transfer, and, following the third negative pregnancy scan, holding the cows for a further period of 50 days prior to removal from the containment facility.

The Committee similarly accepted that conventional surrogate cows that have given birth to a genetically modified calf may also be disposed of off site. The Committee opted to prescribe a withholding period for such cows of at least 100 days in order to provide consistency with the measures applied to cows which have failed to become pregnant, and to ensure that no foetal blood cells derived from the genetically modified calf remain in the cows.

### **iii. Disposal of milk**

Additional information supplied by the applicant proposed several methods of disposal of milk derived from genetically modified cows. These included, incineration or autoclaving of small quantities of milk from induced lactation of genetically modified cows at 6-9 months of age, and for surplus milk from lactation of mature genetically modified cows, disposal via incineration, spraying onto pasture, or digestion in an effluent digester, either on-site or by a local effluent disposal company.

Issues were raised by a number of parties to the application regarding the potential risk of contamination of ground water as a result of spraying milk derived from genetically modified cattle onto pasture. However, the issue of pollution of groundwater (or other water) as a result of the land disposal of milk is a matter that is managed under the Resource Management Act (RMA) 1991. Disposal of milk via treatment and spraying onto pasture is not a possible route for the escape of heritable material and therefore a matter more appropriately dealt with under the RMA.

Control conditions on this approval therefore provide for disposal of waste milk and cream by effluent digester or incineration on-site, or spraying onto pasture on-site following treatment in order to destroy any cells present in the milk. It is also required that milk derived from genetically modified cattle and used in further experimentation be retained on-site and be disposed of in the same manner when no longer required for experimental purposes.

# ASSESSMENT OF THE RISKS (MAGNITUDE AND PROBABILITY OF ADVERSE EFFECTS) AND OTHER ADVERSE EFFECTS OF THE ORGANISM TO THE ENVIRONMENT AND HUMAN HEALTH AND SAFETY

The risks and adverse effects considered were those identified as potentially significant, having regard for those matters set out in clauses 9 and 10 of the Methodology. Risks were considered in terms of the requirements of clause 12 of the Methodology, including especially the assessment of magnitudes and probabilities, the impact of uncertainty and the impact of risk management.

The evidence available was largely scientific in nature and was considered in terms of clause 25(1) of the Methodology. This evidence comprised principally that provided by the applicant and additional evidence set out in the Evaluation and Review Report prepared by the staff, or by submitters. The scientific evidence relevant to the consideration was not generally in dispute so in this respect clauses 29 and 30 of the Methodology did not apply. The exception is in regard to horizontal gene transfer and that is discussed further below.

It is noted that risks and adverse effects that particularly relate to Māori are considered in the next section of this decision. (from page 21).

## **Animal Welfare**

A number of issues related to animal welfare were raised at the hearing. While animal welfare is not referred to directly in the Act or the Methodology, the Committee considered that the scope of clauses 9 (a) and 9(b) of the Methodology was sufficiently wide to potentially encompass such matters. Issues raised included those associated with:

- (a) the delivery of calves by caesarean section
- (b) induced lactation of animals aged 6-9 months
- (c) aberrant behaviour of genetically modified cattle as against conventional cattle.

The applicant is required to comply with the relevant sections and regulations of the Animal Welfare Act 1999, and the Animal Welfare Advisory Committee (AWAC) and National Animal Ethics Advisory Committee (NAEAC) guidelines administered by MAF.

Any organisation using animals in research must hold a Code of Ethical Conduct (CEC), approved by MAF, that sets out the policies to be adopted, and procedures to be followed by the organisation and its Animal Ethics Committee (AEC). Furthermore every project involving the manipulation of animals, including those undertaken in the course of the development and field testing of genetically modified cattle covered by this application, must be approved by an AEC.

The Committee's view is that animal welfare issues are properly covered by other legislation, and that animal welfare does not need to be considered any further as a risk under the HSNO Act. Section 12 of the Methodology thus does not apply.

Because of concerns expressed it is nevertheless required, as a condition on this approval, that the applicant report from an animal welfare perspective on issues including; behaviour traits of genetically modified cattle as against unmodified cattle in the field test; number and explanation of caesarean sections performed for genetically modified cows; and any issues associated with the induced lactation of genetically modified calves.

In addition the applicant is required to forward to ERMA New Zealand any reports provided to the relevant AgResearch AEC.

## **Risks to the Biological and Physical Environment**

It is noted that this section of the decision considers only biological and physical risks. Metaphysical risks which may arise under s6(d) of the Act are considered in the next section of this decision.

### **Soil and Water Environments**

Potential risks to the biological and physical environment identified above include:

- risks to the soil environment through the uptake of genetically modified material by soil organisms, and
- contamination of the water supply with genetically modified material.

These risks can be considered together because they have the same nature (clause 12(a) of the Methodology refers) and derive from the same source ie. the release of cells containing genetically modified material (transgenes) in wastes and the hypothetical transfer of transgenes to soil organisms through the mechanism of Horizontal Gene Transfer (HGT). Horizontal Gene Transfer is the term used for the direct transfer of DNA between organisms ie. not via normal reproductive processes. The exact significance of HGT in different situations is uncertain.

There was no scientific evidence put forward on HGT in the context of soil and water contamination. (HGT in the context of human health is examined in the next section of the decision, page 17.) However, the Committee considered this possibility in any case, particularly in the context of controls on the disposal of milk (see page 13). Its view was that such transfers were only a hypothetical possibility, and if they did occur would do so at an extremely low rate. Given the fixed location and limited duration of the contained research, the quantum of transfer likely to occur was considered to be negligible. Given the vast quantity of DNA naturally falling on the soil, the likelihood that the transgene would be transferred rather than any other DNA was considered to be extremely low in any case. And the Committee's view was that even if transfer did occur there would be no discernable adverse effects. The Committee concluded therefore that the likelihood of adverse effects through the process of Horizontal Gene Transfer was negligible (clauses 25 and 29 of the Methodology refer.)

In regard to the management of any risks that might exist (clause 12(d) of the Methodology refers), the Committee dealt with any possible effects on soil organisms of disposal of milk and other cattle biological material by imposing controls requiring destruction of biological material. The issue of cattle dung and urine was also discussed with a view to requiring chemical treatment of the pasture but it was concluded that this mode of treatment was likely to be more detrimental to the environment than occurrence of a hypothetical possibility of the transgenes escaping into

the environment through faeces or urine and subsequently being incorporated in the genome of soil micro organisms.

The magnitude of these risks is considered to be very low, even after taking account of uncertainty i.e the upper bound of the uncertainty range still leads to a conclusion of very low magnitude although it is not possible to quantify this (12(e) of the Methodology refers). Importantly this means that even if the controls failed, the possible effects would not be such as to make this cause by itself to decline the application (12(b) and 12 (c) of the Methodology and s45(a)(ii) of the Act refer).

The impact of the proposed containment regime and the hypothetical nature of the risks is such that the probability of occurrence of the adverse effect is very low (12(c)).

The Committee therefore concludes that the risks posed by the organism to the soil and water environments, in the context of the application, are negligible.

## **Other Risks to the Environment**

There is no identifiable risk to the environment from cattle within the containment facility itself. For any effects on the wider environment to be realised as a result of this containment application, the organism or any heritable material must first escape into that environment, and either form a self-sustaining population or enter the national herd undetected.

Consideration was given to whether genetically modified cattle if they escape would have any effects on the natural environment different to those of conventional cattle. Cattle are domesticated animals and cannot interbreed with other native fauna. In addition, genetically modified cattle do not pose any threat to native or valued flora greater than that of conventional cattle. The risk is not significant in any terms.

## **Risks to Non-genetically Modified Cattle**

The other potential risk identified above is that of adulteration of non-genetically modified herds of cattle by mating with genetically modified cattle. The nature of the risk (12(a) of the Methodology refers) is that such adulteration may produce unwanted genetically modified offspring of a valued species.

In this respect it is noted again that cattle are domesticated animals, and the probability of cattle produced as a part of this trial, escaping undetected and establishing a self-sustaining population is very low (clause 10(e) and (f) of the Methodology refer). All conventional cattle are required to be double tagged, and all genetically modified cattle are required to carry both visible ear tags and a sub-cutaneous microchip. All cattle would therefore be readily identifiable, and able to be retrieved.

Controls to which this approval is subject, require that, in the event of unintended or accidental release or escape of genetically modified cattle, the applicant shall recover the escaped cattle. Furthermore, if there has been any possibility of mating occurring, any possible resulting pregnancies will be aborted, and if not successful, the affected cattle shall be slaughtered and disposed of on-site. Alternatively, any potentially affected cows shall be identified, destroyed,

and be disposed of in accordance with the provisions specified in the controls. Eradication would therefore be relatively easy to achieve (clause 10(f) of the Methodology refers).

Thus, the probability of escape, and then entry into the national herd, through undetected breeding is very low.

The options and proposals for the management of the risk are set out in the section above on the adequacy of containment and explained in detail in the controls attached to the decision (12(d) of the Methodology refers). These controls include amongst other things the provision of a containment facility which exceeds the requirements of the relevant standard No 154.03.06 issued by the MAF Biosecurity Authority.

The magnitude of the risk is considered to be no more than low, even after taking account of uncertainty i.e the upper bound of the uncertainty range still leads to a conclusion of low magnitude although it is not possible to quantify this (12(e) refers). Importantly this means that even if the controls failed, the possible effects would not be such as to make this cause by itself to decline the application (12(b) and 12 (c) of the Methodology and s45(a)(ii) of the Act refer).

The impact of the proposed containment regime is such that the probability of occurrence of the adverse effect is very low (12(c)).

The Committee therefore concludes that the risks posed by the organism to the national herd of non-modified cattle in the context of the application, are negligible.

## **Risks to Public Health**

Identified risks to public health comprise:

- (a) consumption of milk/meat derived from genetically modified cattle
- (b) potential future use of products derived from genetically modified cattle

### **Consumption of milk/meat derived from genetically modified cattle**

Potential adverse effects could arise from the direct effects of ingestion of MBP (including horizontal gene transfer of the antibiotic resistant marker gene to gut micro-organisms), indirect consequences of the genetic modification, and the potential transfer of the gene to gut epithelial cells (clause 12(a) of the Methodology refers).

Reference to horizontal gene transfer (HGT) as being of no significance to the application was made by the applicant (clause 25 of the Methodology refers).

Some submitters disputed the view of the applicant on HGT in this context, although only one reference was provided in support of this dispute (clause 16 of the Methodology refers). This reference was a report of the effects of digestion on genetically modified bacteria containing antibiotic resistance genes using an artificial human gut. The results had not been published in the scientific peer reviewed literature and thus had no scientific standing (clause 29 of the Methodology refers).

The MBP cattle approved under this decision contain a gene sequence that codes for the human protein MBP. The gene is expected to be expressed primarily in the mammary glands of the cattle (and therefore the protein is expected to be present in the milk), but the gene will also form part of the genome of the cattle and exist in every cell.

The sequence coding for the expression of MBP in cattle has been artificially constructed, and contains not only DNA based on human sequences (coding for the protein itself) but also regulatory sequences derived from other sources.

MBP is a protein and will be inactivated by cooking and by gastric acid and digestive enzymes. Therefore, it is unlikely that in the event of ingestion of meat or offal, or milk from genetically modified cattle, there would be any risk to human health.

If MBP is not degraded and is absorbed, on the basis of current knowledge no adverse effect is anticipated.

The magnitude of the risk is thus considered to be extremely low (clause 12(b) and 12(c) of the Methodology refer).

However, a key issue is the likelihood of human consumption. The herds produced under this approval are to be maintained in containment, and there is no intention for the meat offal, or milk from genetically modified cattle, or cattle that have given birth to genetically modified calves, to enter the human food chain. The probability of genetically modified cattle escaping is very low and the probability of genetically modified beef, offal or milk entering the human food chain undetected is thus also very low.

The probability of occurrence of adverse effects depends on both escape of the organism and consumption of its milk/meat and is thus assessed as very low given the stringency of the proposed containment regime clause (clause 12(c) of the Methodology refers).

The overall risk is therefore considered to be extremely low even after taking account of uncertainty. This conclusion is not subject to any significant uncertainty i.e the uncertainty bounds are tight (clause 12(e) refers). Even if the organism escaped the possible effects would not be such as to make this cause by itself to decline the application (clauses 12(b) and 12(c) of the Methodology and s45(1)(a)(ii) of the Act refer).

The Committee therefore concludes that the risk posed by consumption of the organism to public health, in the context of the application, is negligible.

### **Potential future uses of products derived from genetically modified cattle**

The applicant will not be producing any products as a result of this field test. If in the future pharmaceutical products were to be developed from MBP cattle, approvals would be required from the relevant pharmaceutical regulatory authorities, in addition to further approvals under the HSNO Act, before production of any product for release could be undertaken. There are thus no immediate risks to be considered.

## Long-term Unanticipated Effects

The Committee received a number of submissions expressing concerns that the processes and consequences of genetic modification are insufficiently established for the applicant to be able to provide assurance that there will be no unanticipated long term adverse effects on either the environment or human health.

These submissions covered several grounds:

- the uncertainty of genetic modification as a science obliged the Committee to take a precautionary approach under the Act
- field testing, in addition to being risky in itself because of risks of the organism escaping, was in any case unlikely to extend over a sufficient period of time for long term adverse effects to materialise, so that eventual release applications would proceed without adequate evaluations of the risks
- the possibility of escape during the field test period, or of inter-breeding following release would jeopardise New Zealand's expanding organic agricultural and horticultural industries, and its 'clean green' image
- the possibility of long term adverse effects materialising well into the future had to be taken into account in considering the well-being of future generations
- the proposition that if the Committee is able to take into account hypothetical benefits then it should also take into account hypothetical risks.

In terms of the Act the Authority can consider these kinds of issue in relation to:

- the requirement under *section 5(b) of the Act* (repeated in clause 9(b) of the Methodology) to recognise and provide for the maintenance and enhancement of the capacity of people and communities to provide for their own economic, social and cultural well-being and for the reasonably foreseeable needs of future generations
- the requirement under *section 7 Act* to take account of the need for caution in managing adverse effects where there is scientific and technical uncertainty about those effects.

The Committee does not dismiss any of the concerns expressed. However, concerns regarding scientific uncertainty, and potential long term adverse impacts on future generations are more relevant to release applications than to an application covering the conduct of research in containment. There is no scientific evidence presented in the submissions regarding the potential long term consequences of the genetic modifications proposed in the present application. However, based on the evidence provided by the applicant and by staff in the Evaluation and Review Report, the Committee's view is that this will not result in adverse consequences for the environment, human health, or future generations while the research is undertaken in containment. The caution required of the Committee relates to the adequacy of the containment conditions and management regime. In this regard the Committee considers the risks to be negligible for current and future generations alike.

The Committee considers however, that the applicant should take note of the concerns expressed, and be prepared to address them in the event that an application is made to release products or material derived from genetically modified cattle.

At that time the possibility of long term adverse effects can be expected to be more determinative. This decision relates only to the proposed development of the applicant's research, and should not be taken as any commentary on the safety of any products that may be derived from genetically modified cattle in the longer term.

# ASSESSMENT OF RISKS TO THE RELATIONSHIP OF MĀORI AND THEIR CULTURE AND TRADITIONS WITH TAONGA; PROVIDING FOR ECONOMIC, SOCIAL AND CULTURAL WELLBEING; AND THE APPLICATION OF THE PRINCIPLES OF THE TREATY OF WAITANGI

The need to take account of the relationship between Māori and their culture and traditions with their ancestral lands, water, sites, waahi tapu, valued flora and fauna and other taonga is set out in Section 6(d) of the HSNO Act is expanded in clause 9[c](iv) of the Methodology. Section 5(b) of the Act is also relevant. Section 8 of the Act requires the Authority to take account of the Principles of the Treaty of Waitangi.

Issues in this area are dealt with separately in this decision from other risks, because they formed a major part of the consideration, and lead to the development of Majority and Minority positions within the Committee.

The current application sought approval to field test cattle containing three different genetic modifications. Two constructs, (casein<sup>plus</sup> and BLG<sup>minus</sup>) have already been approved, but in respect of the third construct, involving cattle containing a genetic sequence coding for a human protein, myelin basic protein (MBP), the consideration was adjourned whilst the Committee sought further information from the applicant and Ngāti Wairere, the Tainui hapū which claims manawhenua over the land on which the research will be carried out. Information was sought on the steps which might be taken to ameliorate Ngāti Wairere's concerns regarding the proposed research programme. This information was sought in accordance with s 58 of the Act and clause 23 of the Methodology.

Extensive consultations were held between the applicant and Ngāti Wairere prior to the hearing on all three components of the application, and representatives of Ngāti Wairere attended the hearing, at the invitation of the Authority, and made a presentation involving a number of witnesses. This included a tohunga whose presentation was given, by request, in a closed session. Discussions were subsequently held between the applicant and Ngāti Wairere, and with staff of the Authority and members of Ngā Kaihautū, culminating in a hui held at the Hukanui marae on 13 May 2000.

In summary, Ngāti Wairere expressed concerns regarding all three constructs on the basis that genetic modification is contrary to their spiritual guardianship of the mauri or life force of all living species. However, their concerns were strongest in relation to the present application.

The application concerns the development of cattle from embryo into which a synthesised gene containing the sequence which codes for human myelin basic protein (MBP) is present. This modification has been carried out in AgResearch's laboratory under authority delegated by ERMA to its Institutional Biological Safety Committee (IBSC). This application deals with the next step of creating cattle from those embryo, initially through cloning and surrogacy techniques, and then conventional breeding, in order to determine whether the protein generated by the inserted gene sequence will be expressed in the milk of subsequent generations of cattle.

Ngāti Wairere believe that genetic modification involving different species is contrary to their tikanga, because it interferes with the whakapapa as well as the mauri of both species. They believe their kaitiakitanga (spiritual guardianship) extends to imported species such as cattle which have a long presence in New Zealand and which could be regarded as a valued species in terms of *section 6(d)* of the HSNO Act.

They also believe that both whakapapa and mauri will be interfered with even though the genetic sequence inserted in the embryo has been synthesised from information obtained from an international gene bank, which will have derived DNA originating from a non-Māori person. They believe that to proceed with genetic modification of any kind, but transgenic modification in particular, may result in members of Ngāti Wairere suffering adverse health consequences and even death.

In the event both the applicant and Ngāti Wairere concluded that the concerns expressed by Ngāti Wairere could not be ameliorated by any action on the part of the applicant, and no new information emerged from the several meetings and hui that took place during the 6 months that the consideration was adjourned. There are a number of measures consistent with Ngāti Wairere's tikanga which the applicant should pursue, as a matter of good practice, regarding such matters as the disposal of offal and other biological material, and these have been incorporated in the controls to which this decision is subject, but they do not ameliorate the basic unacceptability of transgenic modification.

Both Ngāti Wairere and Ngā Kaihautū Tikanga Taiao (the Authority's advisory committee on the provisions of the HSNO Act relating to Māori) recommended that the applicant be advised to withdraw the application at least pending the outcome of the Royal Commission on Genetic Modification, in order to provide time for Ngāti Wairere to further assess the risks of genetic modification technology to Māori, and to understand where it sits with their tikanga. It is not open to the Committee to require the withdrawal of an application and, while the application remains before it, the Committee is obliged, after full consideration, to make a decision.

The decision is not unanimous, but a Majority favour approving the application subject to the controls specified, for the reasons which follow. The contrary view is also outlined below.

## Majority Decision

The consideration of the submissions made by Ngāti Wairere was undertaken pursuant to:

- *section 6(d) of the Act* (repeated in clause 9[c](iv) of the Methodology) which requires the Authority to take into account the relationship of Māori and their culture and traditions with their ancestral lands...and other taonga
- *section 8* of the HSNO Act, which requires the Authority to take into account the principles of the *Treaty of Waitangi*.
- *Section 5(b)* of the HSNO Act which requires the Authority to recognise and provide for the principle of maintenance and enhancement of the capacity of peoples and communities to provide for their own economic, social and cultural well being and for the reasonably foreseeable needs of future generations.

As set out in clause 12 of the Methodology the nature of the claimed adverse effects, its magnitude and probability of occurrence, uncertainty bounds, and options for managing the risks, were considered, in assessing risks in this area.

Clause 25 of the Methodology was relevant to the assessments in this area. Because the risks are principally based in the spiritual elements of Māori culture, scientific evidence is neither relevant nor available. However values and other non-scientific elements of the evidence were considered in accordance with clause 25(2).

### **Section 6 (d) – the relationship of Māori with their culture and taonga and Section 5(b) – economic, social and cultural well being**

Taking into account the relationship of Māori and their culture and traditions with their ancestral lands, water, sites, waahi tapu, valued flora and fauna and other taonga under *section 6(d)* of the Act in the present instance raises different issues than seem to have arisen in cases considered by the Courts under similar provisions of the Resource Management Act 1991.

Those cases have principally involved proposed developments which the relevant iwi have regarded as a potential interference with or affront to waahi tapu on the land concerned, or to the spiritual significance of a particular piece of land, waterway, shellfish bed and so forth. The RMA cases have involved what might be regarded as tangible or physically distinguishable taonga, whereas in the present instance the Authority is required to assess the weight to be given to taonga which are spiritual beliefs themselves, rather than something physically distinct to which spiritual values attach.

Nonetheless the decisions in the RMA cases are instructive. As a generality, the Courts seem to have been reasonably pragmatic in their decisions, within quite wide bounds.

In *Huakina Development Trust v Waikato Valley Authority* [1987] 2 NZLR 190, Chilwell J said in the High Court:

‘Māori spiritual and cultural values cannot be excluded from consideration if the evidence established such links to a particular and significant group of Māori. Nor should the benefit of all New Zealanders be given a degree of absolute emphasis so as to exclude Māori spiritual values from a branch of law, which has an affinity with the Treaty.

The way the Waitangi Tribunal dealt with the concept of Māori spiritual values established that such values could not be dismissed as being something the community could trample on.’

On the other hand, the Court of Appeal (Tipping J) in *Watercare Services Limited v Minbinnick* [1998] NZRMA 113 which dealt with a proposed sewer route crossing waahi tapu, held that:

‘The Court must weigh all relevant competing considerations and ultimately make a value judgement on behalf of the community as a whole. Such Māori dimension as arises will be important but not decisive even if the subject matter is seen as involving Māori issues.... While the Māori dimension, whether arising under *section 6(e)* [of the Resource Management Act] or otherwise, calls for close and careful consideration, other matters may in the end be found to be more cogent when the Court, as the representative of New Zealand society as a whole, decides whether the subject matter is offensive or objectionable....In the end a balanced judgement has to be made.’

In *Mabuta and Ors v Waikato Regional Council* (unreported, 29 July 1998, Environment Court, A91/98, Judge Sheppard) the Court held that:

‘...perceptions which are not represented by tangible effects do not deserve such weight as to prevail over the proposal to defeat it ...’

In practical terms, the Courts seem to have been more prepared to find grounds for protecting waahi tapu or the spiritual significance of a site when there have been other options available to the applicant, but they have moved to protect waahi tapu where they are clearly definable and where:

‘...the value of the relationship of [the relevant iwi] with the subject land, and its traditional and cultural significance for them, is clear and strong’. *CDL Land New Zealand Ltd v Whangarei District Council* [1997] NZRMA 322

In the present instance however, we are dealing with the spiritual beliefs of whakapapa and mauri themselves, which Ngāti Wairere claim govern behaviour in an absolute way, and simply preclude genetic research of the kind proposed by the applicant. There is no alternative course by which the applicant might avoid the claimed affront to these beliefs, except to conduct the research elsewhere and, as we have learned, there are no steps the applicant can take to ameliorate the affront or the consequences claimed. In terms of clause 12(d) of the Methodology this is an instance where ameliorating effects through risk management is not possible. The fact that others in society may attach higher weight to the knowledge to be gained from the proposed research will not change the significance of the beliefs to the group of persons who hold them.

The Majority accepts that the spiritual beliefs as expressed by Ngāti Wairere are deeply held, as are the concerns regarding the consequences of the proposed research proceeding. However, the Majority have questions as to whether the interpretation of their traditional beliefs advanced by Ngāti Wairere is widely held, given that those beliefs would have been developed well before human-kind had any appreciation of the evolution of species by genetic mutation and selection, or of the role, function and separability of genes, and the proteins they code for, or of the scientific possibility of transposing gene sequences between species. Matters of belief of course, can only be determined by the people who hold them.

And the Majority have difficulty in appreciating how the insertion of a synthesised genetic sequence coding for a protein present in humans, should through interference with the whakapapa or mauri of the cattle to be produced, lead to the claimed adverse consequences to Ngāti Wairere.

Thus in accordance with clause 12 of the Methodology, the Majority considers that after considering the uncertainty in the evidence presented the beliefs at issue are unlikely to produce biological and physical effects ie the combination of the magnitude of biological and physical effects and probability of occurrence is such as to produce a negligible risk (clauses 12(a)(b)(c) and (e) of the Methodology).

This leaves the purely spiritual belief-based element of risk to be dealt with. This element of risk cannot be mitigated by the imposition of controls (clause 12(d) of the Methodology). The Majority’s view is nevertheless that the existence of these beliefs, strongly held though they may be, is not sufficient to outweigh the scientific benefits of the research. In this regard the Majority is of the view that while there is some prospect that the knowledge to be gained from the proposed research may eventually be applied in medical research which may lead to benefits for human-kind, such potential benefits should not be taken into account. Rather the Majority

considers the immediate knowledge to be generated by the project to be the appropriate basis for consideration of benefits.

## Treaty of Waitangi

The Majority agree with the submissions from Ngāti Wairere, supported by a number of witnesses and Ngā Kaihautū Tikanga Taiao, that, within the overarching principle of partnership, the principles of the Treaty of Waitangi to be taken into account by the Authority encompass requirements to:

- make informed decisions
- ensure that consultations have been held with Ngāti Wairere to this end
- act reasonably and in good faith
- provide active protection for Māori interests and taonga
- recognise Ngāti Wairere's rangātiratanga over its ancestral lands and taonga.

Ngāti Wairere submitted that whakapapa and mauri, as central elements of their tikanga, are taonga requiring active protection by the Authority, and that to provide this protection, the Authority should decline the application, and thereby disallow the mixing of human and cattle genes, and the corresponding interference with the whakapapa and mauri of the cattle.

Ngāti Wairere submitted further, that in accordance with the principles of partnership, and recognition of their rangātiratanga over their ancestral lands, the determination of what constitute taonga, and whether or not the research programme proposed by the applicant is compatible with their tikanga, rests with Ngāti Wairere rather than the Authority.

On this latter point, the Majority notes that when the same point was argued in *Otararua Hapū v. Taranaki Regional Council* the Environment Court emphasised that *section 8* of the RMA (which is the same as *section 8* of the HSNO Act) needs to be read in the context of the whole Act, and that it does not provide that decisions will be made by Māori in accordance with their values and laws. Accordingly, in the present instance, the Majority considers decisions should be made by the Committee established by the Authority, having fully informed itself of the issues, in accordance with the Act and the evidence before it.

As regards the requirements to consult, to be appropriately informed, and to act in good faith, the Majority believes the Authority has taken considerable care to ensure that these principles have been taken into account. As a general matter the Authority appointed Ngā Kaihautū Tikanga Taiao to advise it on the provisions of the Act affecting Māori, and although in this instance the Majority has not followed the advice given by Ngā Kaihautū Tikanga Taiao, the process of interaction with Ngā Kaihautū has resulted in the Committee being well informed on the matters at issue with Ngāti Wairere.

The Authority specifically requires applicants to engage in consultation and dialogue with the relevant iwi and hapū, prior to lodging their applications and in the present instance the initial consultations between AgResearch and Ngāti Wairere took place over a period of 5 months before the application was lodged. Furthermore, the Authority took the step of inviting Te Kōtuku Whenua, who submitted as Ngāti Wairere, to appear at the public hearing on the application and personally present their views to the hearing Committee.

In addition the Committee adjourned its consideration of the application after the hearing for a further period of 6 months, in order to allow further consultations between the applicant and Ngāti Wairere.

The Committee arranged for members of ERMA New Zealand and Ngā Kaihautū Tikanga Taiao to assist in the consultative process, and this has contributed to the Committee's information on the issues.

In taking into account the need for active protection of whakapapa and mauri as taonga, the Majority notes that spiritual beliefs are different from taonga as they have come to be understood in the cases which have come before the Courts and the Waitangi Tribunal, and are not amenable to active protection in the same way as more tangible taonga.

The decisions of the Courts in the major Treaty cases refer to the Treaty as creating an enduring relationship of a fiduciary nature, and Māori interests which have been found to be subject to the government's obligation of active protection have included land, waters, economic resources such as fisheries and geothermal steam, and more recently the language itself. These are all physically or tangibly definable interests.

The Reports of the Waitangi Tribunal have similarly dealt with either historical claims in respect of land or other economic resources, and the consistency of Government legislation with the provisions of the Treaty which give Māori rangātiratanga over such resources.

As far as the Majority could identify, none of the Treaty cases before the Courts, or the Waitangi Tribunal have addressed the nature of the Government's obligation to actively protect Māori spiritual beliefs, such as whakapapa and mauri, in contrast to tangible taonga with spiritual significance.

In considering the present application, the Majority concluded that active protection as sought by Ngāti Wairere and Ngā Kaihautū Tikanga Taiao would mean that the evaluation of and decisions on applications under the HSNO Act should be made according to the tenets of Māori spiritual beliefs, as these may be defined variously and from time to time.

The Majority concluded that the requirement to take into account the principles of the Treaty under *section 8* does not extend this far. It is one thing to take every effort to respect Māori spiritual beliefs, it is another to ask the whole community to accept them as arbiters of whether genetic research should proceed under the HSNO Act.

This would seem to be consistent with the decisions in the major Treaty cases.

The Privy Council in the *Broadcasting Assets* case [1994] 1 NZLR 513, held:

'Foremost amongst those 'principles' are the obligations which the Crown undertook of protecting and preserving Māori property, including the Māori language as part of taonga, in return for being recognised as the legitimate government of the whole nation by Māori. The Treaty refers to this obligation in the English text as amounting to a guarantee by the Crown. This emphasises the solemn nature of the Crown's obligation. It does not however mean that the obligation is absolute and unqualified. This would be inconsistent with the Crown's other responsibilities as the government of New Zealand and the relationship between Māori and the Crown. This relationship the Treaty envisages should be founded on reasonableness, mutual cooperation and trust. It is therefore accepted by both parties that the Crown in carrying out its obligations is not

required in protecting taonga to go beyond taking such action as is reasonable in the prevailing circumstances.’

In summary therefore the Majority has concluded that taking into account the need to provide active protection for Māori spiritual beliefs does not extend to accepting those beliefs as the determinant of whether the research proposed by the applicant should be approved.

## **Requirement for Further Consultation**

The Majority believes its conclusion that the application should be approved has been derived from a proper application of the requirements of the HSNO Act. In essence, the requirements to take into account the relationship of Māori and their culture and taonga, and the principles of the Treaty do not extend to requiring the community as a whole to accept Māori spiritual beliefs as the determinants of applications to conduct genetic research under the HSNO Act, where the other requirements of the Act have been met.

However, the Act does not provide a sufficient framework within which to address the concerns elaborated by Ngāti Wairere. In brief, the balancing of spiritual beliefs and scientific endeavour is not a matter solely for judicial weighing up. It is not surprising that Ngāti Wairere and the applicant were unable to reconcile the issues involved. They do not lend themselves to point in time decision making, even though the HSNO Act requires this, and this Majority decision will not take the issues away. A broader approach is required to provide a context in which the HSNO Act can operate in dealing with these kinds of issues, and this is a matter which should be addressed in the current Royal Commission’s inquiries.

What is required is time, and on-going dialogue, and reflection and consideration within Ngāti Wairere in particular, but with assistance and support from the applicant, who will undoubtedly be raising similar issues on a continuing basis as it continues its work in genetic research, and perhaps from ERMA New Zealand, the Authority’s functional arm. The process should not be locked into legal discussion of what is required under the Act or the Treaty.

The Majority of the Committee has therefore introduced as a control on the approval a requirement that the applicant establish an on-going Working Group with Ngāti Wairere, to be used by the latter not only to monitor progress with the implementation of the field trial, but also as a source of information on the matters which will contribute to their evaluation of the impacts of genetic modification technology on their tikanga.

The Committee does not consider that the full scientifically researched health risk assessment requested by Ngāti Wairere is practicable, and is not prepared to impose responsibility for it upon the applicant. However, the applicant should note that the issues raised by Ngāti Wairere in this application will not disappear and, while not prepared to require this as a condition of the approval, the Majority recommends that the applicant consider providing support to Ngāti Wairere for the evaluation they wish to undertake of the metaphysical health consequences for their people of genetic research being undertaken on their ancestral land.

AgResearch will undoubtedly have further applications for research involving genetic modification, including transgenic modification. The land on which it is located belongs to Tainui and it behoves AgResearch to facilitate the resolution of the issues which stand between the continued development of its scientific work and the concerns of the iwi which claims mana whenua over the land on which it is conducted.

## Minority View

*Ko te whakapapa tenei  
Mo nga taonga tuku iho a Io matua kore  
Ka moe a Papatuanuku ia Ranginui  
Ka puta ko Tane Mabuta  
Ko Tangaroa  
Ko Tawhirimatea,  
Ko Tumatauenga  
Ko Haumie Tiketike  
Me Rongomatane  
Ko enei nga taonga tuku iho o ratou ma  
Ko matou nga Kaitiaki  
Mo enei taonga*

### Genealogy recites for us

Our divine Inheritance  
Through the union of Earth Mother and the Sky Father  
Who gave birth to our resources  
And entrusted their care into our hands,  
The lands and sea  
The forests and birds  
The animals and plants  
All these treasures  
Bestowed upon us as nurturers  
To sustain people

*Whakapapa* is the foundation on which all tribal Māori values, including spiritual and ethical values are based. It is part of protocol to first know who the people are before looking at any of their values.

*Whakapapa* preserves the blood ties and acts as a birth, death and marriage register, and establishes the family origins of each individual Māori within the *wbanau* (family), through to the *hapū* (sub-tribe) and the *imi* (tribe).

*Whakapapa* is also the method by which *tangatāwhenua* (people of the land) akin themselves to the mountains, rivers and other physical features within the areas where they reside. The origins of the cosmos and the world are also encapsulated and orally recited through *whakapapa* and within this context *whakapapa* establishes the historical precedence of the nation of the Māori people within their territorial boundaries.

*Whakapapa* allows an individual to claim his *tangatāwhenua* and *kaitiaki* status, and his *rangātiratanga* to the natural and physical *taonga* that we as Māori are spiritually charged to conserve; *taonga* which is afforded 'active protection' under the principles of Te Tiriti O Waitangi 1840. This multi-faceted discipline is the most distinguishing characteristic in the Māori world, in that all its organisational relationships were based upon it.

Past decisions of the courts in major Tiriti cases refer to the Tiriti as creating an enduring relationship of a fiduciary nature akin to a partnership, and encompassing an obligation of the Crown of active protection of land, waters, economic resources and *te reo rangātira* (the first

language) which, until more recently was not accepted as a *taonga*. For Māori, the language is the life principle of Māori power, prestige and charisma.

Human life comprises these intangible life principles and transcends into the most sacred of *taonga* to Māori which is recited and re-affirmed in the *whakatauki* (proverb) – ‘*He aba te mea nui? He tangata, he tangata, he tangata.*’ (‘What is the most important thing? It is man, it is man, it is man’).

Upon this basis the Minority supports Ngāti Wairere’s claims, that *whakapapa* is the central, albeit spiritual, value which maintains the *mauri* of all living *taonga*. To compromise the integrity of *whakapapa* by altering the gene structure of species through modifications which could not occur naturally is inherently against *tikanga Māori*. Some Māori are of the view that genetic modification, and particularly the crossing of human genes with other species is abhorrent.

The altering of gene structure is not accepted in the realm of *Atua* and is in breach of the principle of ‘active protection’ of *taonga*.

The Majority holds that such protection does not extend to spiritual *taonga*.

The spiritual values which have guided Ngāti Wairere in their submissions, and which derive from their earliest beliefs, preclude the alteration of *whakapapa* of human-kind by mixing the genetic make-up of humans with other species, and these cannot be changed by contrasting these beliefs with the outcomes of a scientific research programme.

The risks to Māori and their *taonga* of genetic engineering, and in particular the crossing of species barriers and the altering of native fauna and flora, has yet to be assessed in *Aotearoa*, and until such time that this has taken place, the Authority do not have adequate information before them to make an ‘informed decision’. There is an obligation to be appropriately informed, for example as set out in clause 8 of the Methodology.

The Authority has an obligation to consult widely with the ‘Māori experts’ in this area before any other applications which pose such an affront to Māori culture and *tikanga* can be considered.

Ngāti Wairere is one of the many hapū and descendants of the great *waka Tainui*, and are the *kaitiaki* of *Papatuanuku*, their ancestral lands (*whenua tuku iho*), and of the culture and *taonga* which have been handed down to them in written and oral form through *tauparapara*, *whaikorero* and *waiata*. These *taonga* are theirs to uphold, and it is therefore inherently incumbent upon Ngāti Wairere to ensure that their *tikanga* values and culture are expressed in the context of this application - and respected - even though this has involved them in the uncomfortable process of subjecting their sensitive spiritual values to the scrutiny of the Authority in culturally inappropriate surroundings.

There are no criteria established to assess the risks to Māori and allow for the weighing up of the risks and costs against benefits. In the course of the further consideration, the Majority attempted to assess the cultural and spiritual risks (adverse effects) to Māori, by taking into account clause 9(c)(iv) of the Methodology and s6(d) of the Act. However, they concluded that the perceived benefits continued to outweigh the risks and adverse effects to Māori (Ngāti Wairere) and their *taonga*. Ngāti Wairere are entitled to see that the Authority has made a genuine attempt to inform itself of their concerns, and to assess the risks to them in making its decision. The Minority does not consider that these risks have been adequately understood or assessed.

The Minority believe that the six month adjournment resulted in an outcome which clearly showed that there were very significant risks to Ngāti Wairere's cultural, physical and spiritual values and to their health and well-being which were of such a degree, that these risks could not be ameliorated, nor was Ngāti Wairere prepared to consider a compromise.

It is not surprising that the applicant and Ngāti Wairere were unable to reach agreement on measures which might be taken by the applicant to ameliorate the cultural concerns expressed by Ngāti Wairere, or that in hindsight the endeavour was bound to fail. The affront to Ngāti Wairere's cultural values and spiritual beliefs which the proposed research represents can only be avoided by not proceeding with the research, a view which has been strongly supported by Ngā Kaihautū Tikanga Taiao, the Māori advisory committee to the Authority.

The hui held on 13 May 2000 reaffirmed that the cultural issues raised by Ngāti Wairere and others during the hearing, and consequent meetings far outweighed the benefits, ie 'that there may be information derived from the research'.

*Mauri* is the protective power or quality which is present in all elements, the sky, stars, seasons, animals, humans, and all other things. In man it is commonly known as the 'physical life principal'. Should the *mauri ora* (life principle) of man become *noa* (free from tapu, ordinary) or defiled, then his physical, intellectual and spiritual welfare is seriously endangered and he is exposed to many perils. This research poses risks to the *mauri* of the people of Ngāti Wairere, their ancestral lands, water and other *taonga*, including that of the cattle. The protective powers of the *mauri* will cease until restored, if at all, by the appropriate means.

The contamination, or the destruction, of natural features will destroy the *mauri*, and unbalance the *wairua*. Contamination, pollution and all other adverse effects continue to violate these qualities. The genetic inter-relationship of Māori to the environment means that Māori will continue to be affected until contamination ceases and *matauranga* Māori (knowledge) is accorded equal recognition.

The pollution and desecration of *Papatuanuku*, and the contamination of ground water with genetic waste, which is considered to be 'offensive' is a direct violation of the *mauri* and *wairua* of these physical *taonga*, which again breaches the principle of 'active protection'.

The consequences of proceeding with the proposed research can possibly only be captured by those who have an understanding and knowledge of such matters, or who have been sufficiently informed. Ngāti Wairere concludes that illness, (*mate Māori*), *hōpō*, and even death are established phenomena, which may befall their *hapū*, and therefore cannot be lightly discounted.

This is reinforced in the present instance by the Minority agreeing with Ngāti Wairere, that the benefits of the proposed research are hypothetical, and therefore insubstantial, and the incremental scientific knowledge which may emerge from the proposed research is an insufficient benefit to enable them to accept that they must be prepared to deal with consequences of this gravity.

These spiritual phenomena may be difficult for many New Zealanders to comprehend, but any sensitivity to the impact which tikanga has on the every day lives of Māori requires that its values be respected.

A request by Ngāti Wairere for the applicant to undertake a health risk assessment of the metaphysical effects of this research on their people has not been met. The Minority notes the high cost flowing from the obligation thrust on Ngāti Wairere to provide the information to

support its concerns. However, the Minority contends that in good faith on the part of either the Authority or the applicant, and in view of the extension of time to consider amelioration of risks, the health assessment could have been undertaken and analysed. The Minority considers that this assessment may have gone some way to alleviating the concerns of Ngāti Wairere.

In addition, the hapū will carry the burden on behalf of all Māori, and may experience a period of grieving, not only for themselves, but for past generations who set the *kawa* and *tikanga*, and for future generations faced with the turmoil created by the action of mixing genes between species. And they may endure a state of negative *noa* (powerlessness, helplessness and weakness) until the spiritual affront has been cleansed (*whakanoa*) or the *tapu* lifted.

The affront has already occurred through the insertion of the copy human gene in the laboratory, without Ngāti Wairere's knowledge or consent. It makes no difference to the affront that the gene coding for human protein is a copy, or that the original genetic information was derived from a non-Māori.

The Minority are also of the view that the risks to the relationship between Māori, and in particular Ngāti Wairere, and their *taonga* are significant and that the proposed containment together with the additional controls imposed by the Authority has no bearing on the issues before Ngāti Wairere.

That the applicant's IBSC approved the modification of embryo in this way without informing and consulting Ngāti Wairere is a demonstration of its failure to understand its obligations under the HSNO Act and Te Tiriti O Waitangi.

The views expressed by Ngāti Wairere were supported by Ngā Kaihautū Tikanga Taiao who state that the Authority is obliged under *section 8* of the HSNO Act to take into account the principles of Te Tiriti O Waitangi and to respect the *rangātiratanga* of Ngāti Wairere over their ancestral lands and taonga.

*Section 4* of the HSNO Act (*Purpose of the Act*) is 'to protect the environment and the health and safety of people ... by preventing or managing the adverse effects of hazardous substances and new organisms'. This research poses significant risks to the protection of the environment and the 'health' of the people (Ngāti Wairere).

*Section 6(d)* requires the Authority to take into account the relationship of Māori with their ancestral lands, and their *taonga* which the Minority considers to include intangible *taonga* and the fundamental spiritual values of Māori.

The Minority consider the issue to be one of timing and impact upon Māori culture. We wish to consider the impact of the offence to the spiritual beliefs upon the cultural values and the economic and social welfare of Māori, as required under *Section 5(b)* of the HSNO Act.

*Section 5(b)* requires the Authority to 'recognise and provide for...the maintenance and enhancement of the capacity of people and communities to provide for their own economic, social, and cultural wellbeing'.

Ngāti Wairere expressed views which would lead one to understand that the inability for the hapū to impact upon the proposed research which is offensive to Māori cultural values, would lead to stress-related illnesses.

Notwithstanding the views expressed by the Majority that previous Court decisions did not contemplate that the compact between Māori and the Crown would introduce spiritual values into the legislative framework, we believe that it is clear that the impact of decisions which would have the effect of impacting upon the ability of the community (which includes Māori) to maintain their culture is of concern to the Authority.

The concern for the Minority is that this decision sets a precedent which may make similar decisions more likely, and that in the face of repeated offences against Māori cultural values by such mixing of genes between species, and the impact upon the whakapapa and tikanga, consequential depression and *mate Māori* arising from such repeated trauma will affect the ability of that community to provide for their own economic, social and cultural wellbeing, and affect the relationship between their culture and their ancestral lands.

The Minority reiterates Chilwell J in *Huakina Development Trust v Waikato Valley Authority* [1987] 2 NZLR ‘The way the Waitangi Tribunal dealt with the concept of Māori spiritual values established that such values could not be dismissed as being something the community could trample upon’. The Minority also notes that the High Court decision which resulted in this further consideration found that issues such as this had to be dealt with on a case by case basis.

Ngāti Wairere are not prepared to sacrifice their culture, and/or the health and wellbeing of their people for this research, therefore the Minority supports Ngāti Wairere in their strong opposition to any decision that detrimentally affects the relationship of Ngāti Wairere and their culture and traditions with their ancestral lands, water and other *taonga*.

This application raises moral and ethical concerns for Ngāti Wairere and Māori as a whole. The Authority cannot make decisions on such applications until such time as these concerns have had wider debate.

There is an urgent requirement for the Authority to consult with ‘Māori experts’ in the area of cultural and spiritual risks to Māori, before any other application which presents such an affront to Māori *tikanga*, can be considered.

The Minority recognises that this research proposal effects blatant breaches of the principles of Te Tiriti O Waitangi, and therefore should not proceed.

### **Glossary:**

Atua	God
Hapū	sub-tribe
Hopo	psychological illness
Iwi	tribe
Kaitiaki	guardians/caretakers
Kaupapa	protocol
Kawa	rules
Mate Māori	Māori illness
Mauri	life essence
Mauri ora	life principle
Ngā Kaihautū Tikanga Taiao	The Māori advisory committee to the Authority
Noa	cleansed (from <i>tapu</i> )
Pakeha	foreigner – usually applied to a white person
Papatuanuku	mother earth
Rangātiratanga	self determination

Tangata whenua	people of the land
Taonga	treasures
Tapu	sacred/out of bounds
Tauparapara	sacred chant
Te reo rangātira	the first language
Te Tiriti O Waitangi	The Treaty of Waitangi
Tikanga	rules/the right way
Tūpuna	ancestor (-tral)
Waiata	song
Wairua	spirit
Whaikorero	oratory
Whakanoa	the act of cleansing
Whakapapa	genealogy
Whakatauki	proverb
Whanau	family
Whenua tuku iho	lands handed down (inherited from ancestors)

## ASSESSMENT OF BENEFITS AND COSTS

It is appropriate to deal with the assessment of benefits and costs together as they are similarly associated in clause 13 of the Methodology. Benefits and costs may arise from any of the matters set out in clauses 9 and 10 of the Methodology.

### Benefits

The Majority notes that the principal benefit, as with all research, is the scientific knowledge expected to be gained. Professor Blair comments that “there will be significant new knowledge generated that will assist the scientific community”. In the case of the production and field testing of genetically modified cattle carrying a sequence coding for a human protein, scientific knowledge is expected to be gained in areas including:

- the reproductive biology of cattle, from the implantation of both genetically modified and unmodified embryos into surrogate cows
- whether the cattle express the MBP gene, and secrete the human protein, myelin basic protein (a protein of interest with respect to possible pharmaceutical development), in their milk (this would be a scientific first)
- the composition of the milk resulting from introduction of an artificial human gene into cows
- whether expression of the gene, under the control of a mammary specific promoter, is confined to the mammary gland or whether it is expressed elsewhere
- whether the modification (and phenotype) is inherited as a stable modification in successive generations (leading to the production of second (T2) and third (T3) generation animals that also express the gene product in their milk)
- the stability of single and multiple copies of the transgene following transmission to T2 and T3 animals

Additional indirect benefits likely to accrue as a result of this trial include:

- economic and other benefits to be derived from this research being undertaken in New Zealand, by a Crown owned research institution
- capacity building in this area of technology resulting in the generation of knowledge within New Zealand that may be applied within our particular context, rather than building a reliance on overseas knowledge
- encouragement to this type of innovative research in the field of biotechnology in New Zealand (including the retention of intellectual capital, and a critical mass of science expertise)

For the longer term there may be downstream benefits to be derived should the research lead to commercial applications, including pharmaceutical development, but these will only materialise

as a consequence of second phase research to be undertaken to establish the characteristics of the milk derived from genetically modified cattle, and at this point it would be premature to speculate on what those benefits might be.

Indeed, the Committee acknowledges that the degree of long term benefit to be derived from this research, as with all fundamental research, is difficult to quantify. However, that is not to say that the knowledge accumulated in the research is not beneficial as that information adds to the pool of knowledge from which other benefits flow, and the Committee accepts that exploratory research is an essential prerequisite for scientific progress.

Immediately, and for the purposes of most containment applications therefore, the issue is not so much whether the longer term benefits outlined will be achieved, but whether research leading to those potential benefits is a legitimate and valuable scientific endeavour.

The Committee accepts that given the significance of the dairy and wider pastoral industries in New Zealand, its research institutions should be at the leading edge of research into the genetic factors which control and regulate milk production (including milk composition, quality and enhanced characteristics) and of associated biotechnological innovation, including recombinant research, and technologies of nuclear transfer (cloning) and surrogacy.

The Majority is thus of the view that the application will generate significant immediate scientific (non-monetary) benefits. However, it is in the nature of scientific work that the magnitude is difficult to quantify and subject to considerable uncertainty (clause 13(b) of the Methodology refers) although Professor Blair observes that “there is the potential to provide significant new knowledge and therefore I concur that the benefits are moderate to high”.

In terms of distributional effects (clause (13(c) of the Methodology), the benefits will accrue most immediately to the applicant but can be expected to spread more widely over time. It is noted that the applicant is a Crown Research Institute which is bound by law to undertake research which is to the benefit of New Zealand (CRI Act 1992). It is also relevant to note that the work is being funded by the Foundation for Research Science and Technology, using monies intended for public good research.

## **Costs**

A “cost” is defined in reg. 2 of the Methodology Order as “the value of a particular adverse effect expressed in monetary or non-monetary terms”. For the purpose of this application the Committee has determined that there is only one potential adverse effect which generates a greater than negligible risk; i.e. the adverse effect (or effects) arising from the recognised affront to the spiritual beliefs and values of Ngāti Wairere.

In terms of clause 13(a) of the Methodology, the “cost” or value to be ascribed to this effect is non-monetary and not capable of capture in a simple statement. It is possible that monetary costs could be incurred by those who hold these beliefs and suffer adverse health consequences as a result. However the Majority is not satisfied that the magnitude of the “cost” is significant. In essence the Majority found it difficult to accept a link between the interference with whakapapa or mauri of the cattle, and the severity of the claimed adverse consequences. It did not consider that a scientifically robust health assessment as requested by Ngāti Wairere would be feasible.

This is to be contrasted with the Minority view that serious health consequences for Ngāti Wairere would result, and the breach of the principles of the Treaty was such that the research

should not proceed. In the view of the Minority, the cost resulting from the research proceeding is extremely high.

In terms of clause 13(c) the distributional effects, in terms of both groups in the community and space, will fall onto those who hold these beliefs, most significantly Ngāti Wairere on whose land the research would proceed. The distributional effects over time are not considered to be capable of quantification.

## ESTABLISHMENT OF THE APPROACH TO RISK IN THE LIGHT OF RISK CHARACTERISTICS

Clause 33 of the Methodology requires the Authority to have regard for the extent to which a set of risk characteristics exist when considering applications. The intention of this provision is to provide a route for determining how cautious or risk averse the Authority should be in weighing up risks and costs against benefits. In the case of the present application the relevance of clause 33 is much reduced because the application is “in containment” and it has already been concluded that the containment provisions and other controls will reduce most biological and physical risks to a low level. For these biological and physical risks the extent of the need for caution, over and above the exercise of caution in setting conditions and controls, is not considered to be material to the overall weighing of risks costs and benefits.

Nevertheless it may be useful to observe that for all of the biological and physical risks considered (risks to the environment and to human health and safety) the impact of containment especially is to make involuntary exposure unlikely and to prevent uncontrollable spread. Because the field test will be limited in duration the risks will not persist over time. It is considered that they will generally not be irreversible. On the other hand it is probably the case that the risks are not generally known or understood by the general public. although the significance of this is again much reduced by the existence of containment and that this is a limited field test in a single location.

The affront to Māori spiritual beliefs is another matter. Matters of this sort do not readily lend themselves to the analysis of risk characteristics, as do biological and physical risks. In this case the Majority’s view is that the provisions of clause 33 of the Methodology should be applied in a qualitative way in conducting the combined evaluation of risks, costs and benefits under clause 34 of the Methodology. And that has been done.

## THE OVERALL EVALUATION OF RISKS, COSTS AND BENEFITS

The overall evaluation of risks, costs and benefits set out below was carried out having regard to clause 22 and 34 of the Methodology and in accordance with the tests in clause 27 of the Methodology and s45 of the Act.

Clause 34 of the Methodology sets out the approaches available to the Authority in evaluating the combined impact of risks costs and benefits ie weighing up risks, costs and benefits. However, it is only necessary to include those risks, costs and benefits which are non-negligible.

In this regard the Committee's conclusion is that the biological and physical risks to the environment and human health from the possible escape of the genetically modified MBP cattle are negligible, given the nature, consequences and probabilities of the risks involved, and the extent of the containment and cattle management regime set out in this decision (clause 22 of the Methodology refers). These physical risks thus do not have to be weighed in the balance.

The only remaining risk is that to the relationship between Māori, and in particular Ngāti Wairere, and their taonga. In terms of the affront to spiritual beliefs, this risk is not negligible. It is apparent that at the least it weighs very heavily with some Māori within Ngāti Wairere. However the significance of the risk and thus the cost of the associated adverse effects is a matter on which the Majority and the Minority have a different view. This is discussed further below.

Because the risks as a whole are non-negligible the decision set out below must be made in accordance with clause 27 (not clause 26) of the Methodology.

The Majority considers there to be significant scientific benefits associated with the application.

It is necessary to weigh the scientific benefits of the application against the spiritually based risk to and associated cost of the relationship with taonga. It is evident that there are no common units of measurement available for this so clause 34(a) of the Methodology cannot apply. However it is appropriate to adopt the "dominant risk" approach set out in clause 34(b) of the Methodology. In this respect there is the one dominant risk to be weighed.

The Majority conclude that the risks to the relationship between Māori, and in particular Ngāti Wairere, and their taonga, are not sufficient to justify declining the application, given the counterbalancing scientific benefits to be obtained from the proposed research. This view reflects the judgment that a risk of a purely spiritual nature ie without reasonably evidenced biological and physical effects, should not in this case outweigh the particular scientific benefits. This view takes account of the need to consider risk characteristics, in accordance with clause 33 of the Methodology.

The Minority however conclude that the risks to the relationship between Māori, and in particular Ngāti Wairere, and their taonga, and associated breaches to the principles of the Treaty of Waitangi are more significant than the scientific benefits, and that the application should be declined. This conclusion reflects the view that spiritual beliefs should not be treated as less significant than biological and physical risks, that it is contended that biological and physical risks

and costs are likely to arise in any case, and that the strength of the objection held by Ngāti Wairere outweighs the benefits.

## DECISION

In conclusion therefore

1. Pursuant to *section 45(1)(a)(i)* of the Act, the Committee is satisfied that this application is for one of the purposes specified in *section 39(1)* of the Act, being *section 39(1)(b): Field testing any new organism*.
2. Having considered all the possible effects of the organism in accordance with *sections 45(1)(a)(ii)* and *(iii)* of the Act and pursuant to clause 27 of the Methodology, and based on consideration and analysis of the information provided and taking into account the application of risk management controls specified in this decision, the view of the Majority is that the risks (or costs) of adverse effects associated with the field testing in containment of genetically modified cattle containing the genetic sequence which codes for the expression of MBP, are outweighed by the benefits of conducting the research.
3. The Committee is satisfied that the proposed containment regime together with the additional controls imposed will adequately contain the organism as required by *section 45(1)(a)(iii)* of the Act
4. In accordance with clause 36(2)(b) of the Methodology the Committee records that, in reaching this conclusion, it has applied the balancing tests in s.45 of the Act and clause 27 of the Methodology and has relied in particular on the following criteria in the Act:

Section 5(b) – to achieve the purpose of the Act and to recognise and provide for the maintenance and enhancement of the capacity of people and communities to provide for their own economic, social, and cultural wellbeing and for the reasonably foreseeable needs of future generations;

Section 6 and in particular s.6(c) (public health) and 6(d) (the relationship of Māori and their culture and traditions with their ancestral lands ... and other taonga) and (e) (the economic and related benefits to be derived from the use of the new organism);

Section 8 – the principles of the Treaty of Waitangi

It has also applied the following criteria in the Methodology:

Clause 9(b) [equivalent of s.5(b)] and 9(c) [equivalent of s.6]; clause 10 [equivalent of ss.36 and 37]; clause 12 – evaluation of assessment of risks; clause 13 – evaluation of assessment of costs and benefits; clause 21 – the decision accords with the requirements of the Act and regulations; clause 22(1) – the evaluation of risks, costs and benefits – relevant considerations; clause 24 – the use of recognised risk identification, assessment, evaluation and management techniques; clause 25 – the evaluation of risks; clause 27 – risks and costs are outweighed by benefits; clause 33 – risk characteristics; and clause 34 – the aggregation and comparison of risks, costs and benefits; clause 29 (a) - determination of materiality and significance of scientific uncertainty.

5. The application for field testing of cattle containing the MBP construct is thus approved, with controls, as follows.

# CONTROLS

In order to provide for the matters detailed in Part I of the *Third Schedule* to the Act, *Containment Controls for Development and Field Testing of Genetically Modified Organisms*, the approved organisms are subject to the following controls:

## 1. To limit the likelihood of any accidental release of any organism or any viable genetic material<sup>5</sup>:

- 1.1 The applicant before field testing cattle containing any construct not yet developed, shall obtain development approval, under the Hazardous Substances and New Organisms (HSNO) Act 1996, from the AgResearch Ruakura Institutional Biological Safety Committee (IBSC) and provide a declaration in writing to the Authority verifying that:
  - 1.1.1 the construct and genetically modified embryo has been developed in accordance with an approval under *section 39(1)(a)* of the Act
  - 1.1.2 the construct and genetically modified embryo complies with the requirements detailed in the schedule attached to this decision (Schedule 1)
  - 1.1.3 the genetically modified cell line (nuclear donor) from which the embryo is produced contains the transgene [verified by methods including, but not limited to, the Polymerase Chain Reaction (PCR) or Southern hybridisation analysis].
- 1.2 The field test of genetically modified cattle shall be carried out in a *containment facility*<sup>6</sup> registered by the Ministry of Agriculture and Forestry (MAF) under the Biosecurity Act 1993, in accordance with the MAF Biosecurity Authority Animal Health and Welfare Standard/ERMA New Zealand Standard 154.03.06<sup>7</sup>: *Containment Standard for Field Testing of Farm Animals*.
- 1.3 The applicant shall provide ERMA New Zealand and the facility Supervisor<sup>8</sup> (MAF) with a timetable for the production and field testing of genetically modified cattle approved under this decision, and shall notify ERMA New Zealand and the facility Supervisor, in writing, of any changes to that timetable.
- 1.4 The production and maintenance of genetically modified cattle in the containment facility shall be in accordance with the relevant sections and regulations of the Animal Welfare Act 1999, the Animal Welfare Advisory Committee (AWAC) and National Animal Ethics

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<sup>5</sup> Viable Genetic Material is biological material that can be resuscitated to grow into tissues or organisms. It can be defined to mean biological material capable of growth even though resuscitation procedures may be required, eg when organisms or parts thereof are sublethally damaged by being frozen, dried, heated, or affected by chemical.

<sup>6</sup> The *containment facility* refers to the area where the genetically modified cattle are to be maintained, and that is registered by MAF under the Biosecurity Act 1993.

<sup>7</sup> Any reference to this standard in these controls refers to any subsequent version approved or endorsed by ERMA New Zealand

<sup>8</sup> An Inspector appointed under the Biosecurity Act.

Advisory Committee (NAEAC) guidelines administered by MAF, and the relevant AgResearch Animal Ethics Committee (AEC).

- 1.5 The maximum number of cattle<sup>9</sup> in the field test shall not exceed the capacity of the containment facility as approved under the MAF Biosecurity Authority Animal Health and Welfare Standard/ERMA New Zealand Standard 154.03.06<sup>7</sup>: *Containment Standard for Field Testing of Farm Animals.*, and/or any requirements of the relevant AEC, and should at all times be the minimum number of animals required to obtain statistically significant results.
- 1.6 The total number of cattle in the field test (including cattle containing casein<sup>plus</sup> and BLG<sup>minus</sup> constructs approved in November 1999) shall not at any one time exceed 200 animals.
- 1.7 At all times only persons authorised by the Operator or the Manager shall have access to the containment facility.
- 1.8 All conventional cattle in the field test shall be double tagged (ie by two different ear tags). All genetically modified cattle shall be individually identified by an ear tag for visible identification and also implanted with a subcutaneous electronic microchip to enable individual electronic identification. In the event that subcutaneous microchips cannot be inserted until cattle reach a certain age, cattle shall have two different types of ear tag in place at all times, allowing for immediate identification.
- 1.9 The identification system for genetically modified cattle shall enable the information on the genotype and generation (T0, T1 etc) to be derived from a database maintained by the applicant.
- 1.10 The applicant shall maintain a register with records of identity and fate of all cattle in the field test.
- 1.11 No genetically modified cattle are permitted to leave the containment facility except in accordance with the provisions specified in the MAF Biosecurity Authority Animal Health and Welfare Standard/ERMA New Zealand Standard 154.03.06<sup>7</sup>: *Containment Standard for Field Testing of Farm Animals.*, as described in control 1.2.
- 1.12 All genetically modified cattle (and their offspring) no longer required for breeding and any biological material (including semen and ova) derived from such cattle no longer required for the purpose of this application shall be disposed of on-site in accordance with the requirements of the MAF Biosecurity Authority Animal Health and Welfare Standard/ERMA New Zealand Standard 154.03.06<sup>7</sup>: *Containment Standard for Field Testing of Farm Animals*
- 1.13 Conventional cattle, including recipient cows, may be disposed of off site. Recipient cows that have failed to become pregnant shall not leave the containment facility until 50 days after producing three negative pregnancy tests, performed at approximately 28, 35 and 50 days post-embryo transfer.

Recipient cows that have borne a pregnancy shall not leave the containment facility until at least 100 days after the birth of the calf or the loss of the pregnancy, and the applicant shall

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<sup>9</sup> Including; genetically modified cattle, non-modified cattle and conventional cattle.

verify by means of scanning or palpations that there is no retained foetal material. Should a scan or palpation detect foetal material the animal shall not leave the containment facility and shall be disposed of as for genetically modified cattle (in accordance with control 1.12).

- 1.14 Milking of genetically modified cattle shall be performed within the containment facility and the milk shall be transported, in secure containers to prevent spill, to the laboratory (a *containment facility* registered by MAF in accordance with the MAF Biosecurity Authority/ERMA New Zealand Standard 154.03.02<sup>7</sup> *Containment Facilities for Microorganisms* and operated and managed in accordance with Australian/New Zealand Standard AS/NZS 2243.3:1995<sup>7</sup> *Safety in Laboratories: Part 3: (Microbiology)*, at physical containment level 1 (PC1)) for evaluation. A log of the quantity of milk obtained and its fate shall be maintained and recorded in a register.
- 1.15 All genetically modified cattle no longer required for breeding and any biological material (including semen and ova) derived from genetically modified cattle no longer required for the purpose of this application shall be disposed of on-site<sup>10</sup> by burial, in such a manner which minimises leaching to defined aquifers, and following consultation with Ngāti Wairere.
- 1.16 In the event that operations involving genetically modified cattle cease, all genetically modified cattle in the containment facility shall be destroyed and disposed of in accordance with the provisions specified in control 1.13 above
- 1.17 Conventional cattle may be disposed of off-site, but shall not leave the containment facility until 50 days after the third negative pregnancy test, ie performed at approximately 28, 35 and 50 days post-embryo transfer.
- 1.18 All waste milk, skim milk, and cream shall be disposed of on-site by either an effluent treatment digester, incineration, or by spraying onto pasture following treatment in order to destroy any cells present in the milk.
- 1.19 The containment facility shall be enclosed by double 2-metre high perimeter fences constructed in accordance with the requirements specified in MAF Biosecurity Authority Animal Health and Welfare Standard/ERMA New Zealand Standard 154.03.06<sup>7</sup>: *Containment Standard for Field Testing of Farm Animals*. The inner perimeter fence shall be *electronically monitored and alarmed* (in order that the location of any breach of containment is detected immediately), stock-proof and capable of preventing entry and escape of cattle.
- 1.20 From the end of the current approval period on 23 May 2010 the genetically modified (GM) cattle and/or derived biological material may continue to be held under this approval. However, no further breeding or production of any progeny may be initiated. This approval expires when all the GM cattle are dead.

## **2. To exclude unauthorised people from the facility:**

- 2.1 The applicant shall comply with the requirements contained in the standard listed in control 1.2 relating to identification of entrances, numbers of, and access to entrances, and security requirements for the entrances and the facility.

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<sup>10</sup> On-site refers to any place on AgResearch property within the Ruakura Research Centre.

### **3. To exclude other organisms from the facility and to control undesirable and unwanted organisms within the facility:**

- 3.1 The applicant shall comply with the requirements contained in the standard listed in control 1.2 relating to exclusion of other organisms from the facilities and the control of undesirable and unwanted organisms within the facilities.
- 3.2 In the event of mortality in genetically modified cattle in the containment facility, carcasses shall be immediately removed to prevent access by scavengers and the carcasses shall be disposed of in accordance with the provisions specified in control 1.13.

### **4. To prevent unintended release of the organism by experimenters working with the organism:**

- 4.1 The applicant shall comply with the requirements contained in the standard listed in control 1.2 relating to the prevention of unintended release of genetically modified cattle by experimenters working with the cattle.
- 4.2 No part or product of the transgenic organism shall be ingested by any person at any time.

### **5. To control the effects of any accidental release or escape of an organism:**

- 5.1 In case of unintended or accidental release or escape of genetically modified cattle involved in the field test, the applicant shall recover the escaped cattle to the containment facility. If there has been any possibility of mating occurring, steps shall be taken to abort any possible resulting pregnancies. If abortion is not successful, the affected cattle shall be slaughtered and disposed of in accordance with the provisions specified in control 1.13. Alternatively, potentially affected cows shall be identified and destroyed, and be disposed of in the same manner.
- 5.2 If a breach of containment occurs, the facility operator must ensure that the MAF Inspector responsible for supervision of the facility has received notification of the breach within 24 hours.

### **6. Inspection and monitoring requirements for containment facilities:**

- 6.1 The inspection and monitoring requirements for containment facilities shall be in compliance with the standards listed in control 1.2.
- 6.2 The Operator responsible for maintaining genetically modified cattle in the containment facility, shall report immediately to ERMA New Zealand and the Supervisor (at least within 24 hours) on any event that is likely to be in the public interest, eg unexpected mortality in genetically modified cattle or a breach in security.
- 6.3 The applicant shall provide a comprehensive report to ERMA New Zealand in each December on the progress in the production and field testing of genetically modified cattle, including an inventory, with particular reference to the topics listed in section 4.13 of the MAF Biosecurity Authority Animal Health and Welfare Standard/ERMA New Zealand Standard 154.03.06<sup>7</sup>: *Containment Standard for Field Testing of Farm Animals*.. This report shall also include:
  - 6.3.1 information on animal welfare issues including; behaviour traits of genetically modified cattle as against unmodified cattle in the field test, number and

- explanation of caesarean sections performed for genetically modified cattle; and issues associated with the induced lactation of genetically modified calves
- 6.3.2 information on the stability of the genetic constructs used in genetically modified cattle
- 6.3.3 any reports provided to the local AgResearch AEC.
- 6.4 The applicant shall provide a final report to ERMA New Zealand within 1 month of the death of the last of the GM cattle held under this approval. This shall include:
- 6.4.1 information on the items listed in section 4.13 of the MAF Biosecurity Authority Animal Health and Welfare Standard/ERMA New Zealand Standard 154.03.06<sup>7</sup>: *Containment Standard for Field Testing of Farm Animals*.
- 6.4.2 information on animal welfare issues including; behaviour traits of genetically modified cattle as against unmodified cattle in the field test, number and explanation of caesarean sections performed for genetically modified cattle; and issues associated with the induced lactation of genetically modified calves
- 6.4.3 information on the stability of the genetic constructs used in genetically modified cattle
- 6.4.4 any reports provided to the local AgResearch AEC.
- 6.5 The applicant shall establish and facilitate a Working Group with Ngāti Wairere, to enable Ngāti Wairere to monitor the implementation and progress of the field test, and to provide a forum for the exchange of information on the science of genetic modification.
- 7. Qualifications required of the persons responsible for implementing those controls:**
- 7.1 The applicant shall comply with the requirements of the standards listed in control 1.2 relating to the training of personnel working in the facility.
- 7.2 The applicant shall notify the Supervisor and ERMA New Zealand if there are any changes in ownership of the property housing the containment facility in which organisms under this approval are maintained.

Dr Oliver Sutherland  
Chair

23 May 2001

Amended under s67A HSNO Act  
Jill White  
Chair

27 March 2002

Amended under s67A HSNO Act  
Control 6.4 amended by omitting the words “five years” and substituting the words “nine years”, extending the duration of the approval by four years.

18 May 2006:

\_\_\_\_\_  
Chair

\_\_\_\_\_  
Date

Dr Kieran Elborough

Amendment: November 2006

Changes to controls:

- Addition of footnotes to the containment facility references and the Australian/New Zealand containment facility references to “future proof” the decision
- Standardise the wording of the breach of containment control
- Replacement of the control regarding inspection of facilities by the Authority, its agent or enforcement officers with the standard control

\_\_\_\_\_  
Date: 30 August 2007

Dr Kieran Elborough

**Chair**

Amendment: November 2008

- Addition of control 1.20 to clarify the disposal requirements for genetically modified cattle and derived biological material at the end of the approval period.

\_\_\_\_\_  
Date: 12 November 2008

Dr Kieran Elborough

**Chair**

Amendment: March 2010

- Amendment of control 1.20 to clarify the holding requirements of the genetically modified cattle and derived biological material at the end of the approval period. The Committee noted that in the future, animals and derived biological material held under this approval may be regulated under new approval(s).
- Amendment of control 6.4 to clarify when the final report must be provided to ERMA New Zealand.

\_\_\_\_\_  
Date: 11 March 2010

Dr Kieran Elborough

**Chair**

## SCHEDULE

<b>Organism:</b>	Cattle (MBP)
<b>Construct:</b>	MBP Cattle (insertion of a copy of the human myelin basic protein gene)
<b>Phenotype:</b>	Expression of the human protein myelin basic protein in the milk of genetically modified cattle
<b>Genetic modifications:</b>	The constructs shall contain only genes, promoters and marker sequences provided to the Authority in confidence in the application and additional information provided in confidence on 30 June 1999 (regarding a further milk protein gene promoter sequence)

## Submissions Received: Application GMF98009

<b>Submitter</b>	<b>Contact</b>
1. Chris Todd	Private
2. Multiple Sclerosis Society of New Zealand Inc	Dr Tom Miller
3. Mr V Minter	Private
4. Sue Sinclair	Private
5. Neville Sinclair	Private
6. Janice Molloy	Private
7. Claire Bleakley	Private
8. Eric Beardsley	Private
9. PPL Therapeutics	Mike Aitkenhead
10. Maternity Services Consumer Council	Lynda Williams
11. Federated Farmers of New Zealand Ltd	Susan Redward
12. Oraina Jones	Private
13. New Zealand Biotechnologies Ltd	Robert Welch
14. Tom Veitch	Private
15. E Topp	Private
16. Dennis Enright	Private
17. Patricia Scott	Private
18. Susie Lees	Private
19. David Foote	Private
20. New Zealand Dairy Board	Chris Moller
21. Angeline Greensill	Private
22. Zela Charlton	Private
23. Wendy McGuinness	Private
24. Berylla Berylla	Private
25. New Zealand Food & Beverages Exporter's Council Inc.	Robert Lind
26. Sharon Grace	Private
27. Associate Professor Peter Wills	Private
28. Kabal & Gurpal Singh	Private
29. Noel K Wierzbicki	Private
30. James and Wendy Gunther	Private

### Further Information Specification: Application GMF98009

(In respect of the MBP construct)

18 November 1999

#### 1. From Ngāti Wairere

- (i) information on the measures that Ngāti Wairere could take, or could require to be taken by AgResearch, which would ameliorate the concerns that Ngāti Wairere have expressed regarding the proposed research on transgenic cattle containing the human myelin basic protein (MBP) gene; and
- (ii) information on the collaborative arrangements with AgResearch that would be needed to implement the above measures.

These might include, but not be limited to, the measures outlined in the report of Te Kōtuku Whenua on the AgResearch application and also the proposal for the establishment of a monitoring (Kaitiaki) group.

#### 2. From AgResearch

- (i) information on the steps that AgResearch would take in order to facilitate the amelioration of Ngāti Wairere's concerns regarding the proposed research on transgenic cattle containing the MBP gene.