ENVIRONMENTAL RISK MANAGEMENT AUTHORITY DECISION

Amended under s67A on 22 February 2001, 8 April 2002, 23 August 2007, 28 May 2008, and 18 December 2009.

Application Code	GMF99005	**Original Decision**	20 December 2000
Applicant	New Zealand Forest Research Institute		
Purpose	To field test, in the Bay of Plenty (Rotorua), over a period of 9 years, *Pinus radiata* and *Picea abies* plants genetically engineered for herbicide resistance. The total duration of this project is 11 years.		
Date Application Received	18 June 1999		
Date Application verified	14 July 2000		
Hearing Date	1-3 November 2000		
Considered by	Special Committee of the Authority appointed under *section 19(2)(b)* of the Hazardous Substances and New Organisms Act 1996.		

Decision

The application is approved with controls for a period of 11 years from the date of this decision.

The **organisms** approved are:

Pinus radiata D. Don (radiata pine) and *Picea abies* (L).Karst (Norway spruce)

Construct
Plasmids shall consist of pUC-based vectors containing combinations of the genes and promoters listed in Appendix 1. Plasmids will contain one antibiotic resistance gene and one of the herbicide resistance genes. The herbicide resistance gene shall be under the control of one of the promoters listed in Appendix 1. In addition, one copy of the *uidA* (β-glucuronidase) reporter gene as well as the Cauliflower mosaic virus polyadenylation signal and 3' termination signals from *Agrobacterium tumefaciens* may be included in the vector.

Application process

The application was formally received on **18 June 1999**, and verified on **14 July 2000**, following additional information requests. The application was publicly notified on **19 July 2000** in *The Dominion*, *The New Zealand Herald*, *The Press* and *The Otago Daily Times*. Public submissions closed on **30 August 2000**, and 735 submissions were received relating both to GMF99001 and GMF99005.

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 received, and submissions and comment from other government agencies (including the Department of Conservation). The Ministry of Agriculture and Forestry (MAF) did not respond to a request to make any submissions or comments on this application.

In accordance with section 19(2)(b) of the Hazardous Substances and New Organisms (HSNO) Act 1996, the Authority appointed a Special Committee to determine the application. The Committee comprised Authority members: Dr Oliver Sutherland (Chair), Professor Colin Mantell and Dr Lindie Nelson.

Hearing Review

A public hearing was held on **1-3 November 2000** in Rotorua.

The following parties made submissions to the Committee:

For the applicant:

1. Mr Steve Christensen Legal representative for Anderson-Lloyd
2. Dr Christian Walter Senior Scientist Forest Research Institute
3. Dr Mike Carson Director, Carson Associates Ltd

For ERMA New Zealand:

Erika Anderson Project Leader

For Ngā Kaihautū Tikanga Taiao:

John Hohapata-Oke Deputy Chair, Ngā Kaihautū Tikanga Taiao

Submitters:

1. Nick Fisher
2. Mario Rautner for Greenpeace
4. Dr Neil MacGregor witness for Mario Rautner
5. Susie Lees
6. GE Free presented by Susie Lees
7. Tuhourangi/Te Arawa iwi
8. Jeremy West representing Wendy McGuinness
9. Matthew Evetts
10. Abigail Allen
11. Anne Sommerville presenting for Joanna Paul

Relevant legislative criteria

The application was made under section 40(1)(c) of the HSNO Act 1996. The decision was determined in accordance with section 45, taking into account additional matters to be considered under sections 37 and 44, and matters relevant to the purpose of the Act, as specified under Part II of the Act.

Consideration of the application followed the relevant provisions of the Hazardous Substances and New Organisms (Methodology) Order 1998 (the *Methodology*), with particular regard to clauses 8 (information appropriate to the scale and significance of the risks, costs and benefits) and 26 (dealing with applications where risks are negligible).

Application description

The application is for approval to field test in containment *Pinus radiata* D. Don (radiata pine) and *Picea abies* (L) Karst containing genetic modifications to confer herbicide resistance. The purpose of the proposed field test is to evaluate herbicide resistance in genetically modified *P. radiata* and *P.abies* to determine the stability and integration of new genes, and what influence field conditions have on these expressions. The field test will be carried out on the Forest Research Institute (Forest Research) campus in Rotorua. The duration of the field test is 9 years, plus two years of post-trial monitoring.

P. radiata and *P. abies* will be, or in some cases have been, modified in the laboratory to produce genetically modified *P. radiata* and *P. abies* embryos. A total of four transformation events are planned, as listed in Appendix 1 of this decision. Each transformation event will result in a number of transgenic lines. The genetically modified embryos will be placed into liquid nitrogen for cryopreservation. To develop trees, embryos are removed from cryopreservation and tissue culture techniques are used to develop plantlets. These plantlets are spray tested with the herbicide to confirm resistance.

For the purpose of calculating the age of trees in this application—including the age when trees are to be removed from the field test— the date when the embryo is clearly identifiable and transferred to germination medium in tissue culture is considered tree age zero, T=0.

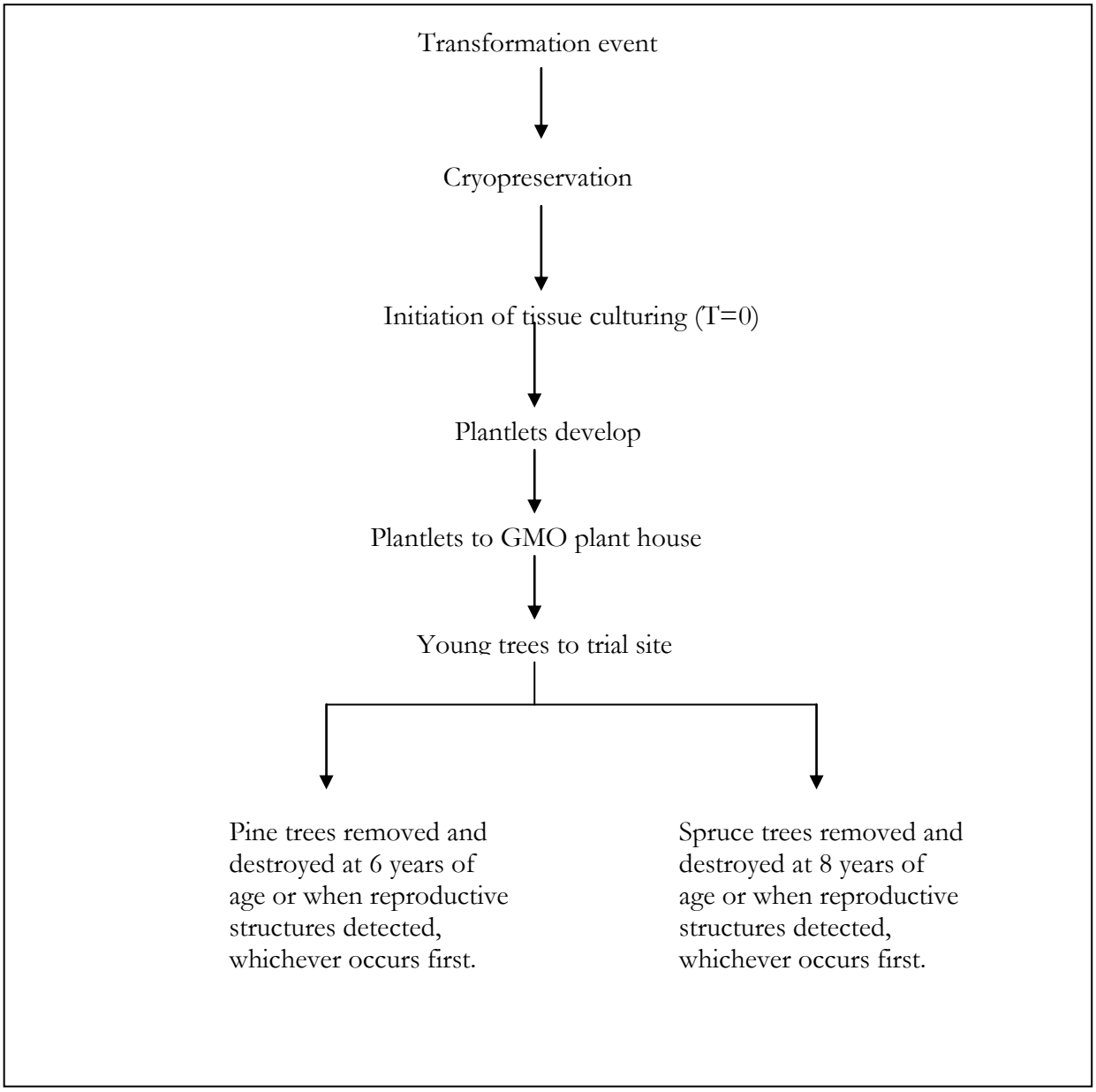
The field test will comprise up to 330 genetically modified pine trees over the period of the trial. The field test site has capacity to hold 330 trees at any one time. The applicant intends to have three types of *P. radiata* and three types of *P. abies* trees in the field test site: genetically modified trees, non-transgenic controls, and fillers. Once a particular location has been used for a genetically modified tree, it will remain empty for the remainder of the trial. All trees will be monitored regularly to detect and remove any developing reproductive structures.

Trees will be removed as soon as reproductive structures are detected. The maximum age of trees in the field will be 6 years for *P. radiata* and 8 years for *P. abies*. *P. abies* are not expected to initiate reproductive structures during the trial, however *P. radiata* may begin to form males cones. If reproductive structures are detected on trees of either species, the particular trees will be removed.

At the time of their removal, all the genetically modified trees will be cut to ground level. The trunk and all branches will be removed from the site and either incinerated, autoclaved, or held in containment in the laboratory. Stumps left in the field will be monitored for two years to detect any re-growth.

Forest Research has agreed to delay any planting of genetically modified trees until the Royal Commission on Genetic Modification has completed its investigation and the current voluntary moratorium on field trials is lifted. This approval allows flexibility in relation to the length of time the genetically modified trees spend in the plant house versus the field, by placing controls requiring removal of the trees from the field based on the age of the tree or the onset of reproductive structures.

Figure 1: Sequence of events from transformation to removal of trees from the trial site



Development Approvals

The applicant claims that approval to develop the genetically modified radiata pine and Norway spruce to be used in this field test was given under delegated authority via application GMD00070 and approval GMD00612-613. The Committee considers that application GMD00070 is ambiguous, and consequently requires the applicant to obtain a new approval

from the Forest Research Institutional Biological Safety Committee that explicitly covers herbicide resistance genes as well as growth of the plantlets in PC2 containment.

Jurisdiction to consider the application as a *field test in containment*

It has been argued by a submitter that this application is not properly a field test because the definition of field test refers to the retrieval or destruction of heritable material.

Definition of field test

The HSNO Act regulates three categories of activity in relation to GMOs: development, field test, and release. In accordance with the purpose of the Act (section 4), which focuses on management of effects, these categories should be taken as a continuum, i.e. with no gaps between them.

'Field test' is defined in section 2 of the Act as:

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

A field test is an intermediate stage between a development and a release. In a development, there is no requirement for environmental realism ('conditions similar to those of the environment into which the organism is likely to be released') while in a release there are no restrictions on the movement of the organism (no containment controls). The function of a field test is to study the organism in a realistic environment without committing that organism irretrievably to the environment. Hence the 'clean-up' limb of the field-test definition: 'from which the organism or any heritable material arising from it, could be retrieved or destroyed at the end of the trials'. This requirement ensures that the management of effects achieved through containment controls during the trial is not negated after the trial by the organism remaining at the site. The emphasis here is not on escape but on what happens when the trial is over, as there would be little point in having strong containment during the trial if there were not mechanisms to also deal with the organism at the end of the trial period.

The Act envisages the possibility, however undesirable, of an organism escaping from a field test. Section 45(1)(a)(ii) requires the Authority to determine whether the beneficial effects of having the organism in containment outweigh the adverse effects of the organism should it escape. In addition, the standard for containment during the trial is set at 'adequate' under section 45(1)(a)(iii).

If the mere possibility, however remote, of an organism not being retrieved at the end of the trial disqualified a proposal from being a field test, the field test category would be redundant. It would never be able to be used, as 100% guarantees are not available. Activities under the Act would be limited to developments and releases. While some might argue that this is a good thing, it is clearly not what the law currently provides for.

Provided there is a sound, reliable method of retrieving or destroying heritable material remaining at the site at the end of a trial, the Committee does not think the application is brought outside the definition of a field test. At the end of this trial the applicant proposes to cut the trees to ground level and remove all trees and their branches from the site. Regeneration

from stumps has never been recorded for *P. radiata* and *P. abies* and the trial does not involve the formation of mature seed.

The Committee considers that the proposed method to destroy or retrieve genetically modified *P. radiata* and *P.abies* at the end of the trial will be effective.

Heritable material

The reference to 'heritable material arising from an organism' does not refer to all biological material produced or shed by the organism, but to material that could be passed on. This would usually be by breeding but could include other 'naturally-occurring' means such as horizontal gene transfer. According to the *Shorter Oxford* dictionary, the basic meaning of heritable is 'able to be inherited', and to inherit is to 'derive or possess' (for example a characteristic) by transmission from a progenitor. 'Transmit' means to pass on, especially by inheritance or heredity.

This 'passing on' is important and distinguishes heritable material from other biological material. The Committee is of the view that "heritable" means that the material must be of a directly heritable nature.

The Committee acknowledges that it would be difficult to contain all biological material, such as pine or spruce needles, within the field test. The Committee does not consider *P. radiata* vegetative matter other than pollen or seed to be heritable material. In some alpine habitats *P. abies* has been observed to produce roots from attached lower branches that touch the ground, but regeneration from fallen branches has not been reported. Regeneration from lower branches would be easily detected during site monitoring. Therefore, the Committee considers that the only relevant heritable vegetative material for *P. abies* is also pollen or seed. The issue then becomes one of escape of genetically modified pollen or seed, or movement of genetic material via horizontal gene transfer. As discussed below, escape from the field test of pollen, seed or genetic material transferred horizontally is considered very unlikely, taking into account the containment controls and the current scientific evidence.

Key Issues

The Committee's consideration of the application encompassed those issues relevant to the application. The Committee considered that the key issues associated with this application are:

1 Length of the trial

2 Relationships with Māori.

Length of the trial

The proposed field trial will last up to 11 years, including the post-trial monitoring period (although *P. radiata* will only be grown in the field to a maximum age of 6 years and *P. abies* to a maximum age of 8). Under these circumstances the Committee considered that a key issue is the long-term maintenance of effective quality control and, in particular, monitoring and removal of reproductive structures.

With the exception of GMF99001, the Authority has never previously been asked to approve a field test of genetically modified plants that extends over such a long time period. Conceivably, few of the present staff, either scientific or technical, will oversee all 11 years of the project. Controls for containment must endure possible changes in management, funding, staffing levels and supervision, research direction, and even the existence of Forest Research and its IBSC as separate entities. The Committee needs to be assured that if circumstances change such that containment controls cannot be maintained, then all the genetically modified trees will be cut down, removed and destroyed, and the site will be monitored for a further 2 years.

Reporting requirements

Forest Research will maintain full responsibility for the field trial and propose appointing a principal investigator who shall oversee the trial and ensure that the controls imposed by this decision are adhered to throughout the duration of the trial. The principal investigator shall be a person with experience and knowledge of genetically modified trees.

The principal investigator's role shall be to:

- Carry out and supervise planting and analysis,
- Establish and supervise the monitoring regime to remove reproductive structures,
- Establish and supervise the trial plan (this to be produced before the trial begins),
- Supervise and train relevant staff, with a role in reviewing staff performance,
- Provide reports to the Institutional Biological Safety Committee, ERMA New Zealand and MAF, and
- Provide regular quality assurance and reporting of the field trial, which will be incorporated within the annual report.

Any change of principal investigator or changes in the management structure of Forest Research that may affect the management of the trials shall be notified to ERMA New Zealand. Refer to control 1.2.

Manuals and trial plans

Forest Research Institute has acknowledged and developed responsibilities and methods at the time of making the application for monitoring the field test. The applicant proposes that the trial will be monitored over the full period with at least monthly inspections in which observations relating to the growth, damage by insects or pathogens and development of reproductive structures will be observed and recorded in a logbook on each visit. The Committee requires weekly inspections of the trees in the field test, throughout the year, to detect and remove reproductive structures. Forest Research has addressed the issue of staff training in Section 4 of their containment manual which ensures that staff are adequately trained or properly supervised by the Laboratory Operator who will also keep written records of training provided for handling of the genetically modified organisms in the laboratory.

The Forest Research containment manual (section 2.8) also includes emergency procedures should any material escape from the laboratory, or natural disasters occur.

The principal investigator will produce a trial plan, which shall include a staff training plan for personnel involved with the field trial, primarily aimed at the detection and removal of reproductive structures, but should also encompass procedures relating to the laboratory and the plant house. This trial plan should be incorporated within the containment manual in the next

update (due when the controls imposed by the Committee are implemented) and be made available to all staff involved with the trial. The trial plan should incorporate the plans below in Table 1.

Table 1: Plans to be incorporated within the trial plan

Trial Plan should include:		**Control**
Staff training plan	This plan will detail the steps to be taken to train personnel involved in the laboratory, plant house and field trial research, particularly in the recognition and removal of reproductive structures.	Control 7.3
Contingency plan	This plan should outline the steps to take to secure the trial site and recover or destroy viable material in the event of natural disasters, premature ending of the trial or loss of key personnel.	Control 7.3
Inspection plan	The principal investigator shall produce an inspection regime in order to detect and remove any precocious reproductive structures that may form, and this includes weekly searches for developing male cones. This plan will also provide contingency plans if staff are away to ensure inspection is always carried out.	Control 7.3
Inventory plan and log	All genetically modified trees removed from the plant house shall be counted, and then re-counted when planted in the field. Records of the counts shall be available for inspection by the Supervisor.	Control 2.4

The applicant and principal investigator shall in their annual report to ERMA New Zealand and MAF specifically comment on the continuing viability of the project, any incident of interference with the field trial, the method of managing the incident and the outcome resulting from this incident, and the plan of activities for the coming year.

The Committee considers that the containment manual incorporating the proposed management regimes indicated above, together with the controls, ensure the maintenance of effective quality control and containment for the duration of the field trial.

Relationship with Māori

Forest Research's consultation with Māori on its molecular biology research was initiated in 1995, when the institute was laying the groundwork for an application to the Interim Assessment Group (IAG) for a field trial of genetically modified *P. radiata* containing a selectable marker gene (*npt II)* and a *uidA* reporter gene (β-glucuronidase). Discussions with the late Mr Te Kuru o Te Marama Waaka and Mr Rangipuawhe Maika resulted in a letter from the Te Arawa and Mataatua Forestry Accord (17 April, 1997) indicating their consent to the intended field trial.

Further inquiry by the IAG on the mandate of the Te Arawa and Mataatua Forestry Accord revealed that the Accord had in the meantime been disestablished and that the land on which the

trial was to be conducted was under claim from several groups. In its report to the Minister for the Environment (17 December, 1997) the IAG subsequently stated that it ".... considers that FRI has started a relevant and ongoing consultation with the appropriate local hapu," and recommended approval of the trials. The Minister notified Forest Research of his approval on 19 December 1997, and the trials were subsequently planted.

Then, in September 1998, Forest Research established the Forest Research/Māori Consultative Group which included six representatives of local iwi and which, to some extent at least, formalised the relationship between the institute and both Te Arawa whanui and Tuhourangi iwi. To date this has not been based upon an agreed Memorandum of Understanding between the parties.

Forest Research's consultation in respect of the present application was initiated in mid-1999 through correspondence with the Te Arawa Māori Trust Board, prior to the application being lodged. Forest Research saw this as "... a continuation of consultation with Te Arawa on an earlier field trial with transgenic *P. radiata*". However, the Board signalled that Forest Research should consult with the local iwi, prompting the institute to initiate dialogue on the matter with the Forest Research/Māori Consultative Group in May 2000. No further comment was received from the Te Arawa Māori Trust Board on the applications.

Following a meeting at which the transgenic research for this application was discussed, the Māori members of the Consultative Group advised Forest Research on 8 June 2000, that although they viewed the proposal " ... at face value ... to be a trial of low risk and with minimal cultural impact for Māori ...." they were not in a position to provide an assessment of risk against outcomes of importance to Māori and did not have sufficient information to form a view on the applications. On 29 August, 2000, a representative of Tuhourangi iwi, including Ngāti Wahiao, and other hapu of Te Arawa, including Ngāti Hurunga Te Rangi, Ngāti Taeotu, and Ngāti Kahu hapu of Ngāti Whakaue, sub-tribes of Te Arawa, registered with ERMA New Zealand their interest in attending a hearing on the applications. Shortly thereafter, and prior to the hearing, Tuhourangi iwi held two hui at which Forest Research staff described the planned research and field trials and presented a draft Memorandum of Understanding which was developed in conjunction with the Māori Consultative Group and which aimed to clarify the future relationship between the parties.

In reviewing this course of events, Ngā Kaihautū Tikanga Taiao, in their report to the Committee, stated that they concurred with the comment in ERMA New Zealand's Evaluation and Review report that Forest Research had made sufficient effort to consult with relevant iwi, and encouraged Forest Research to develop further its relationship with Tuhourangi iwi and Te Arawa.

Six representatives of Tuhourangi iwi attended the public hearing on the application in Rotorua on 2 November 2000, including 4 members of the Māori Consultative Group and one member of Te Arawa Māori Trust Board. In summary, the deputation noted their longstanding and close relationship with Forest Research (previously Forest Research Institute), acknowledged the value of forestry research in general, reminded the Committee of the willingness of Māori to adopt new technology for their advancement, but expressed caution at genetic technologies stemming, they explained, from their lack of knowledge of the risks that such research might pose to Māori values and to biodiversity. Key points emerging from the two consultation hui were that putting human genes into other species was a particular concern, and that if the present applications were to be approved, strict controls should be imposed and iwi involved in their implementation.

In considering these very clear messages from Tuhourangi iwi, the Committee has not perceived direct opposition to the proposed work. The affected iwi clearly value research aimed at furthering the best interests of the forestry sector (in which they have substantial interests) and have a longstanding and close relationship with Forest Research; they are not averse to the adoption of new technologies (noting that Māori have always experimented and developed or adopted new technologies themselves); but they have a caution about genetic manipulation that derives principally from their lack of practical knowledge of molecular biology, and of the risks and benefits of its application. At the same time, Tuhourangi iwi have a strong desire to enhance their relationship with Forest Research by way of a formalised Memorandum of Understanding, which they see will provide a framework for their direct involvement in the management of the proposed research and controls on its implementation. To ensure this control 7.5 in this decision requires the applicant to involve Tuhourangi iwi in the implementation of this field test.

Forest Research has undertaken not to plant transgenic trees in the trial site until the Royal Commission on Genetic Engineering has concluded its deliberations. The Committee considers that this hiatus of several months provides time for further dialogue between Forest Research and Tuhourangi iwi that should enable the iwi to gain greater clarity of the nature of the research and its inherent risks and benefits, and to conclude a Memorandum of Understanding between the parties.

Adequacy of containment

In accordance with sections 45(1)(a)(ii) and 44(b) of the HSNO Act, the Committee considered the adequacy of containment and the ability of genetically modified *P. radiata* and *P.abies* to escape from containment. The Committee's consideration encompassed:

- escape as a result of failure to detect and remove reproductive structures
- escape as a result of deliberate action
- horizontal gene transfer.

Escape as a result of failure to detect and remove reproductive structures

Pollen escape

As noted by the applicant, unintended pollen release could result from:

- inefficient monitoring resulting in failure, over a prolonged period of time, to detect and remove developing male cones, or

- natural disaster making the field trial area inaccessible during pollen maturation.

The Norway spruce trees are expected to be pre-reproductive, since they will be removed by the time they are age 8, and initiation of flowering does not occur until trees are 15 years or older. Most of the *P. radiata* trees will also be pre-reproductive, however the period in the field does encompass the expected initiation of sexual maturity in *P. radiata*.

Failure to remove maturing male cones on genetically modified trees could lead to the production and release of genetically modified pollen. Male cones in *P. radiata* can be differentiated from other vegetative structures well before reproductive maturity. The time period from when an immature pollen cone can be identified until pollen is released is

approximately 8-10 weeks. All male cones are to be removed as soon as they are detected. Male cones of *P. abies* are also able to be differentiated well before they reach reproductive maturity, and any that form are to be removed as soon as they are detected. Any genetically modified *P. radiata* or *P. abies* trees producing male cones (or female cones) are to be cut down and removed from the field test.

There is, in addition, uncertainty regarding the effect of the inserted genes on the onset of sexual maturity in the genetically modified trees. This uncertainty arises because the method of insertion may have unanticipated secondary effects. In view of the possibility of precocious development of reproductive structures, the Committee requires weekly monitoring throughout the year of all the genetically modified trees in the field test. The monitoring is to be carried out by personnel who are competent in the detection and removal of reproductive structures in *P. radiata* and *P. abies*.

In addition, to facilitate detection and removal of reproductive structures, the genetically modified trees shall be trimmed so that they grow no higher than three metres.

Taking into account the pre-reproductive nature of most of the plants in this field test, and the controls in place to monitor for regular and precocious development of male cones, the Committee considered that the likelihood of pollen derived from genetically modified *P. radiata* or *P. abies* escaping is very low.

Seed escape

This field test will not involve the production of mature female cones. In the unlikely event that female cones do develop and mature unobserved on genetically modified *P. radiata*—a process requiring two years, during which the cone is closed—there would be the possibility of seeds being shed that contained genetically modified material. The applicant provided evidence that shed pine seeds generally fall within 100 metres of the parent plant. There is, therefore, a reasonable likelihood that if these seeds germinated, the seedlings would be contained within the Forest Research site and would be identified and destroyed before they reached maturity.

As with *P. radiata,* female cone maturation in *P. abies* takes several years and seed generally falls near the parent tree (OECD 1999), so that there is a reasonable likelihood of any spruce seedlings being contained within the Forest Research site. Since Norway spruce is not a common plantation tree it is very likely that any seedlings can and will be able to be identified and destroyed before they reach maturity.

Taking into account the controls, including weekly monitoring and tree shaping, and the pre-reproductive nature of most of the plants in the field test, the Committee concluded that the probability of escape of genetically modified seed is very low.

Escape following deliberate action

The Committee considered the potential for escape of genetically modified *P. radiata* and *P. abies* as a result of deliberate action such as theft or sabotage from the field test site.

The field test will be located within the Forest Research campus and will be indistinguishable from other field trials. The field trial will also be within a fenced area of the Forest Research campus, which will deter inadvertent or unauthorised access. The Committee is satisfied that, under these circumstances, the likelihood of escape of genetically modified trees due to sabotage or theft is very low.

As a part of the management of the field trial and controls imposed on this approval, the applicant is required to inspect the field test site on a regular basis. Should any disturbance be detected, Forest Research is required to endeavour to recover and destroy any removed plants (refer control 6.1).

Trees are unlikely to survive physical disturbance. In addition, they will not have mature cones on them, so adverse effects resulting from removal of the plants, such as pollen or seed release, are highly unlikely to arise.

Under the monitoring regime and the controls imposed in this decision, the Committee concluded that the likelihood of sabotage or inadvertent action resulting in the loss of plants or genetically modified material from the plant house or the field test site is low, and adverse consequences would be minimal

Horizontal gene transfer

Several submitters expressed concern about horizontal gene transfer, particularly the use of antibiotic resistance genes in trees that, in future, could limit the effectiveness of these antibiotics.

Transfer to soil microorganisms and mycorrhizal fungi

Horizontal gene transfer is known to occur naturally between some soil micro-organisms under some conditions, but it has not been extensively studied (Dröge, et al. 1999). There is very little information about horizontal gene transfer in New Zealand environments. Natural transfer of genetic material between *Rhizobium* species in New Zealand has, however, been reported (e.g., Sullivan, et al. 1995). Based upon overseas studies, horizontal gene transfer is likely to also occur between other species of microorganisms in New Zealand.

Horizontal gene transfer is of particular relevance in the context of this field test as the applicant proposes, following completion of the planting period for each tree, removing the above ground plant material and leaving the stumps and roots to rot in the ground. In addition, beneficial mycorrhizal fungi are found in association with the root systems of *P. radiata* and *P. abies*. These mycorrhizal fungi are able to penetrate the roots of radiata pine and Norway spruce plants so consequently are in close contact with root cells and have the potential to acquire genetic material from the trees.

In order for horizontal gene transfer to occur from the genetically modified trees to soil microorganisms, a sequence of individual events would have to occur (see below). The Committee notes that some laboratory experiments have demonstrated that transfer of antibiotic

resistance genes from genetically modified plants to soil microorganisms can occur under some conditions at low frequency.

For horizontal gene transfer to result in the transfer of a gene capable of producing an active gene product (protein), the following sequence of events would have to occur:

- DNA (containing a modified gene) would have to survive in the soil intact and/or,
- DNA would have to be transferred to, or taken up by, other organisms from the roots of the plant, or from plant material shed into the surrounding soil;
- a complete and active form of the modified gene(s) would have to be taken up by the microorganism and integrated into the microorganism genome;
- the foreign DNA would have to be expressed in the microorganism;
- microorganisms containing the foreign DNA would have to experience a selective advantage.

The Committee considers that the probability of this sequence of events occurring, based on current scientific evidence, is low.

Transfer to gut bacteria of animals

A similar sequence as described above would have to occur for genetic material to transfer from genetically modified trees to microorganisms present in the gut of herbivores, following consumption of genetically modified plant tissue.

Following ingestion of plant material, the excised gene would have to survive the digestion processes of the animal's gut in order to be taken up intact by gut microorganisms. A complete and active form of a modified gene would have to be taken up by the microorganism, and this gene sequence could then have to be inserted behind an appropriate promoter and other regulatory sequences in the genome of the microorganism.

The Committee considers that the probability of this sequence of events occurring is low and therefore considers that it is unlikely that there will be transfer of genes derived from these genetically modified trees.

Ability of the organism to establish a self-sustaining population

P. radiata

Radiata pine is a monoecious species that relies on wind to disperse pollen. Seed is normally contained in serotinous cones that open under hot dry conditions and shed seed. Genetically modified *P. radiata* is therefore capable of establishing a self-sustaining population via the spread of seed. In addition, release of pollen could fertilise non-transgenic trees, and some resultant seedlings could carry the genetic modifications. *P. radiata* hybridizes naturally with one other species *P. attenuata* though this species is not commonly found in New Zealand.

As discussed above, the Committee considers that the likelihood of pollen escaping from the proposed field test and resulting in the establishment of a self-sustaining population of genetically modified *P. radiata* is extremely low.

P. abies

As in radiata pine, Norway spruce relies on wind pollination, and seed maturation and seed shed require dry warm conditions. Norway spruce is uncommon in New Zealand. It has no close relatives in the indigenous flora and no successful crossings with native trees have been observed. *P. abies* is only known to naturally hybridize with *P. jezoensis* and *P. koraiensis* which are not commonly found in New Zealand, although artificial hybrids with other *Picea* species have been formed. Since Norway spruce is a less common tree in New Zealand than radiata pine the likelihood of a self-sustaining genetically modified *P. abies* population establishing will be extremely low.

Ease of eradication

Ease of eradication of genetically modified trees depends on the ease of detection and, subsequently, the ease of destruction.

Detection of transgenic plants

The applicant provided evidence that *P. radiata* seeds generally fall within 100 metres of the parent plant. Norway spruce seeds also generally fall near the mother tree. There is, therefore, a reasonable likelihood that if seeds were produced from the trees in the field test and these germinated, then the seedlings would be contained within the Forest Research site and could be detected and destroyed before they reached maturity. Controls imposed under this decision require the applicant to prepare contingency plans to manage accidental release of plants outside the field test site.

There is the possibility that seedlings could establish beyond the limits of the Forest Research campus as a result of animals carrying and depositing seed off the campus, or from seed formation as a result of escaped pollen. While detection of any plants arising from such seeds would be unlikely, the survival and development to maturity of such escaped seeds is, for reasons outlined above, very unlikely.

Physical or chemical destruction

P. radiata and *P. abies* plants used in this field test will be resistant to either the herbicide "Escort" (a sulfonylurea herbicide) or to "Buster" (glufosinate-ammonium, also known as phosphinothricin), but they will be susceptible to other common herbicides and can also be destroyed by cutting off the plant at ground level. Coppicing or regeneration from stumps has never been observed in *P. radiata* or *P. abies*

The Committee concludes that while escaped transgenic seedlings may not be easily detected off-site, the likelihood of such escape occurring is very low, rendering the risk minimal.

Effects of the organism on the environment and public health

For any effects on the environment or public health to be realised as a result of this field test, the organism or heritable material must first escape into the uncontrolled environment. The principal issue to be considered therefore is whether the escape of such material is possible, and

whether controls can be imposed that would effectively prevent the organism or its heritable material from escaping containment. This issue has been dealt with above (pp 10-12)

In addition to the issues discussed above, the Committee considered the following potential risks to the environment and public health:

- inseparable organisms
- use of CaMV 35S promoter
- spread of antibiotic resistance
- spread of herbicide resistance
- pollen allergenicity
- risks to New Zealand's 'clean green' image
- long-term unanticipated effects.

Inseparable organisms

The Committee considered the potential effects of any inseparable organisms, in accordance with section 45(1)(a)(ii) of the HSNO Act and noted that all the transgenic material used in this application will be generated from sterile tissue cultures and maintained in the GMO plant house where it will be checked for any disease or associated insects prior to planting. Any inseparable organisms associated with this trial will be the same as those associated with non-modified *P. radiata* and *P. abies* already in existence in New Zealand.

Use of the cauliflower mosaic virus (CaMV) 35S promoter

The applicant will use the cauliflower mosaic virus (CaMV) 35S promoter to control some of the genes in the modifications of both *P. radiata* and *P. abies*. The safety of this promoter has recently been questioned, and several of the submitters commented on this. The 35S promoter is a DNA element that controls the expression of some of the CaMV genes. It is termed a strong constitutive promoter, which means that it generally results in high-level expression of the genes that it controls and these genes may be active in many cells.

Submitters have raised concerns that use of the CaMV 35S promoter could:

- lead to the development of CaMV in *P. radiata* and *P. abies*; and
- recombine with infecting viruses to produce virulent new diseases, either in *P. radiata* and *P. abies*, or in other organisms (e.g. insects, herbivores, microorganisms) through transfer of the CaMV 35S promoter via horizontal gene transfer.

Available evidence suggests that *P. radiata* and *P. abies* are not susceptible to viruses, and in particular are not susceptible to infection by CaMV (which is a virus of brassicas). Presence in the modified pine and spruce of a promoter sequence derived from the CaMV cannot in itself cause a viral infection because it is not capable of producing viral products. The promoter does not affect the virus' host range so that it is very unlikely that a recombination event between the CaMV promoter and another virus would affect viral host range or infectivity. Since no viruses are reported from radiata pine or Norway spruce it is very unlikely that use of the CaMV promoter will result in reactivation of viruses in the genetically modified trees, or the generation of new viruses by recombination.

In previous decisions involving organisms containing the CaMV promoter the Authority noted that to date there is no evidence received that the CaMV promoter has a human health risk associated with its use. More recent debate in the scientific literature has not provided additional evidence to suggest changing this conclusion.

Spread of antibiotic resistance

The application proposes the use of two different genes conferring resistance to antibiotics. The *nptII* gene confers resistance to the aminoglycoside antibiotics (kanamycin and neomycin) and *bla* confers resistance against some beta-lactam antibiotics (such as ampicillin). Submitters expressed concern that the presence of large numbers of trees containing the antibiotic resistance genes, and horizontal gene transfer of these genes to bacteria, could limit the effectiveness of these antibiotics.

Uses in medicine

Kanamycin is not used widely in medicine due to widespread resistance and to its toxicity; neomycin is used topically in medicine and has veterinary applications. The beta-lactams, however, are a very important class of antibiotics in human medicine, although the *bla* gene does not confer resistance to all of the beta-lactam antibiotics currently used. Ampicillin is, however, used for a range of medical and veterinary treatments (Read 2000).

Resistance in soil microorganisms

Antibiotics occur naturally in soil ecosystems and antibiotic resistance occurs in some soil microorganisms. The *nptII* gene, which confers resistance to kanamycin, is widespread in overseas environments (Nap *et al.* 1992), and since it occurs in some strains of the bacterium *Escherichia coli*, which is very common in humans and animals, it is very likely to also be in New Zealand. Resistance to ampicillin is reported in some New Zealand soils, although the mechanisms for resistance have not been studied (see Connor). The Committee notes that antibiotic resistance genes have been introduced into New Zealand soils by a range of microorganisms, such as *Rhizobium* bacteria. For example, agricultural field studies at Massey University have introduced resistance genes against rifampicin, streptomycin and spectinomycin into pasture (MacGregor. *et al.* 1982).

Transfer of antibiotic resistance genes

Further proliferation of these antibiotic resistance genes would require they be transferred from radiata pine to soil microorganisms as a result of horizontal gene transfer and be subject to a positive selective pressure. As discussed elsewhere in this decision, based upon experimental evidence the Committee considers that horizontal gene transfer from plants to microorganisms may occur under some conditions, although at low frequency.

Selective pressure

The spread of resistance to any of these antibiotics as a result of the proposed field trial is likely to require continuing contact with the relevant antibiotics at levels necessary to exert a selective pressure. This will not occur in the field trial.

Taking into account the above, the Committee concluded that the risk of increased levels of antibiotic resistance associated with the use of the *nptII* and *bla* genes in genetically modified

trees is negligible when set against the widespread resistance to these antibiotics in the human gut and/or in soil micro-organisms.

Spread of herbicide resistance

The field trial will use two different genes conferring resistance to herbicides. The ALS gene which confers resistance to sulfonylurea herbicides, e.g. "Escort", and the *bar* gene which confers resistance to glufosinate ammonium herbicides, e.g. "Buster".

Submitters expressed concern that the use of herbicide resistance genes could lead to the development of "superweeds", that is plants that cannot be controlled by these herbicides. Such plants could potentially arise from cross-pollination or horizontal gene transfer and lead to plants with resistance to one or both of the herbicides.

Since it is very unlikely that the radiata pine or Norway spruce will cross-pollinate other species, in the event that pollen is inadvertently released the development of herbicide resistant trees will require fertilization of another radiata pine or Norway spruce tree. If a tree outside of the trial site was fertilised with pollen from one of the genetically modified trees then seedlings resistant to one of these herbicides could potentially develop. The likelihood of pollen escape has been discussed above, and is considered to be very low, so that the Committee considers that development of herbicide resistant trees outside of the trial is very unlikely.

Recently, cases of multiple herbicide resistant canola plants have been reported, and these were the result of cross-pollination of different herbicide resistant canola plants. For this to occur in this trial would require either the crossing of wilding genetically modified trees carrying the different herbicide resistance genes, or the cross-pollination of trees within the trial. As noted above, pollen escape and the development of wilding trees outside of the trial site are considered very unlikely, so that maturation and cross-pollination between two herbicide resistant trees would be very unlikely. The Committee considers that cross pollination between trees in the trial will also be very unlikely because this would require not only the inadvertent release of pollen but also the concurrent presence of receptive female cones.

Given the controls imposed by this decision the Committee considers that spread of herbicide resistance by cross-pollination is very unlikely.

As noted earlier in this decision the Committee considers that the likelihood of horizontal gene transfer from plants to microorganisms is low. Consequently, transfer of the herbicide resistance genes from the genetically modified trees to bacteria and then subsequent transfer to other plants would require additional steps, and the Committee considers that spread of herbicide resistance by horizontal gene transfer would be very unlikely.

If plants did acquire resistance to both herbicides, either through cross-pollination or horizontal gene transfer, then application of these herbicides would be necessary for an environmental effect to be observed. Other herbicides would be able to be used to eradicate such resistant plants. The Committee notes that herbicides are not currently used on plantation pine or spruce trees so that widespread application of herbicides near the trial site is very unlikely, and the development of multiple herbicide resistant plants would be very unlikely.

Pollen Allergenicity

The Committee considered that the only potential risk to public health associated with this application arises from allergenicity to pollen (especially pine pollen) since pollen from Norway

spruce has not been reported to be allergenic in New Zealand. While the likelihood of a change in allergenicity is uncertain pollen is not expected to be released during this trial, and controls have been designed to ensure this, so that the likelihood of pollen escape is very low. Also, the field test involves only a relatively small number of trees so that even if they were to produce pollen the amount free to circulate in the air would be infinitesimal compared to production from thousands of adjacent forest trees, and the magnitude of an effect would be minimal.

Risks to New Zealand's 'clean green image'

Submitters raised the prospect that the proposed field trial would jeopardise New Zealand's "clean-green image", suggesting adverse effects to the organic sector and tourist industry. A further concern was that the Forest Stewardship Council has developed an accreditation system for sustainable production forestry that excludes production from genetically modified trees.

Although the Committee does not dismiss such concerns, it considers that they are more relevant to a release application than to an application for a field test in containment. The Committee notes that New Zealand's organic exports have expanded rapidly in the last few years, while the first field trials of genetically modified crops date back to 1988. No evidence has been presented to suggest that the existence of field trials of genetically modified crops has adversely affected either export demand for New Zealand's organic produce or inbound tourism.

Long-term unanticipated environmental and health effects

Submissions were received 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 Authority to take a precautionary approach under the Act,
- the possibility of long term adverse effects materialising well into the future has to be taken into account in considering the well being of future generations.

The Committee does not dismiss any of the concerns expressed. However, concerns regarding scientific uncertainty, and potential long term adverse impacts on future generations like allergenicity are more relevant to release applications than to an application for a contained field test. 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 genetically modified radiata pine or Norway spruce trees.

Precautionary approach

Greenpeace and others submitted that the application should be declined on the basis of the Biosafety Protocol[1], and in particular the precautionary principle reaffirmed in the preamble to that Protocol. That principle is Principle 15 of the Rio Declaration, which reads:

> *In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.*

The basic requirement of the Biosafety Protocol is found in Article 2:

> *The Parties shall ensure that the development, handling, transport, use, transfer and release of any living modified organisms are undertaken in a manner that prevents or reduces the risks to biological diversity, taking also into account risks to human health.*

The Protocol clearly envisages that member states will develop and use genetically modified organisms. Approval of this application would therefore not of itself be inconsistent with the Protocol.

The Committee notes that it is not necessary to determine the nature of New Zealand's obligations under the Biosafety Protocol, as consideration of the precautionary principle falls within section 7 of the HSNO Act. Section 7 requires the Authority to take into account the need for caution in managing adverse effects where there is scientific and technical uncertainty about those effects.

There is some scientific uncertainty regarding the potential consequences of the genetic modifications proposed in the present application. However, the Committee are satisfied that the containment controls placed on the field trial. In this regard the Committee considers the risks to be negligible for current and future generations alike.

As discussed in this decision, the Committee considers that this application poses little threat of adverse effects, and even less threat of serious or irreversible adverse effects, after taking into account containment controls.

Benefits and costs

The benefits of this application relate to scientific information to be gained from the field test. There are no direct financial or commercial benefits either to Forest Research or to New Zealand from conducting this trial.

The applicant has identified the following benefits of the field test:

- To obtain scientific data on herbicide resistance in conifers
- To obtain scientific data on the growth characteristics and behaviour of genetically modified *P. radiata* and *P. abies* in a field situation and over a time period extending beyond that possible in a greenhouse.

[1] The Biosafety Protocol is not yet in force. New Zealand has signed, but not ratified it .

The applicant notes that the trial is designed to obtain data on expression of genes involved in herbicide resistance in conifers and the potential effects on the growth and development pathways of the plants. The applicant notes that this will be the first field test worldwide on herbicide resistance in conifers, and will contribute to maintaining Forest Research's leading edge in conifer genetic engineering. The data collected will also contribute scientific information to the public debate on genetic engineering in forestry.

In the longer term, data obtained from this field test may contribute to other benefits related to the forestry, but the Committee does not consider these to be relevant to this application.

The Committee notes that several submitters expressed concern about the effects of genetically modified trees on the environment and the need for independent assessment of effects. The Committee considers that this field test provides an opportunity to conduct further research on the long-term effects of genetically modified trees on soil microorganisms. The applicant provided evidence at the hearing that Forest Research intends to conduct research on horizontal gene transfer, either themselves or in collaboration with other research institutes.

The Committee notes that, given the containment controls, the costs of this field trial will be borne by the applicant.

Overall conclusion

Pursuant to section 45(1)(a)(i) of the Act, the Committee was satisfied that this application was for one of the purposes specified in section 39(1) of the Act, being section 39(1)(b)*: Field testing any new organism*. The applicant presented information which established that the application was indeed for a field test, namely to observe growth characteristics under field conditions.

The Committee is satisfied that the proposed containment regime, together with the additional controls imposed by the Committee, will adequately contain the genetically modified *P. radiata*, *P. abies* and any heritable material. Escape of genetically modified trees or heritable material is very unlikely, and establishment of undetected seedlings outside the field test is considered to be even more unlikely.

The Committee gave particular consideration to the length of the trial and the views of Tuhourangi iwi. The overall length of the trial is 11 years, including the post-trial monitoring period. To maintain effective quality control and, in particular, be assured that effective monitoring and removal of reproductive structures continues throughout the trial, a principal investigator will be appointed who shall have responsibility for meeting the containment controls, including the preparation of a trial plan and annual reporting to ERMA New Zealand. Controls require ERMA New Zealand to be advised of any changes in the principal investigator or changes in the management structure of Forest Research that may affect management of the field test.

Tuhourangi iwi expressed caution about genetic technologies, while acknowledging the value of forestry research. They indicated their interest in furthering the relationship with Forest Research, and being involved in the implementation of the controls for this field test. Controls in this decision require involvement of local iwi, and the Committee considers that the coming months (prior to any planting of trees in the field) provides time for further dialogue between Forest Research and Tuhourangi iwi.

Having considered the possible effects of the genetically modified *P. radiata* and *P. abies* in accordance with sections 45(1)(a)(ii) and (iii) of the HSNO Act, the Committee is satisfied that the proposed containment regime and additional controls will adequately contain the organisms. The Committee considers that the risks associated with this field test are negligible, given the nature and extent of the containment and management regime set out in this approval. The Committee, having regard to clause 33 of the Methodology conclude that, taking into account the ability of the genetically modified *P. radiata* and *P. abies* to escape from containment as in section 44(b) of the HSNO Act 1996, the beneficial effects of having the organisms in containment outweigh the likely adverse effects of the organisms.

In accordance with sections 45(1)(a) and 45(2), the application to field test genetically modified *P. radiata* and *P. abies* is approved with controls. These controls are specified below.

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*, this application is approved subject to the following controls:

1. Qualifications required of the persons responsible for Implementation of controls:

1.1 The applicant shall inform all personnel involved in the field tests of genetically modified trees of the controls imposed by the Committee.

1.2 The applicant shall inform the facility Supervisor[2] and ERMA New Zealand of any matters which may effect the long term management of the field test including:

i) changes in the principal investigator responsible for the field trial

ii) changes in the management structure of Forest Research that may affect the management of the trials.

2. To limit the likelihood of any accidental release of any organism or any viable genetic material:

2.1 Before field testing of genetically modified trees containing any construct specified in Appendix 1 attached to this decision, the applicant shall obtain development approval including approval to maintain genetically modified trees in a facility approved and operated in accordance with the MAF/ERMA New Zealand Standard 155.04.09[3] *Containment Facilities for New Organisms (including GMOs) of plant species*, and Australian/New Zealand Standard AS/NZS 2243.3:1995[3] *Safety in Laboratories:* Part 3(*Microbiology),* physical containment level 2 (PC2). The applicant shall verify to ERMA New Zealand in writing that:

i) The genetic constructs and genetically modified plant tissue have been developed in accordance with an approval under Section 39(1)(a) of the Hazardous Substances and New Organisms Act (1996).

ii) The genes, promoters and transformation events are those specified in Appendix 1.

2.2 The field test of genetically modified radiata pine and Norway spruce shall be carried out in a *containment facility*[4] registered by the Ministry of Agriculture and Forestry (MAF) under the Biosecurity Act 1993, in accordance with the MAF/ERMA New Zealand Standard 155.04.09[3] *Containment Facilities for New Organisms (including GMOs) of plant species*.

2.3 All genetically modified trees removed from PC2 containment shall be counted, and then re-counted when planted in the field. Records of the counts shall be available for inspection by the facility Supervisor.

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[2] An inspector appointed under the Biosecurity Act.

[3] Any reference to this standard in these controls refers to any subsequent version approved or endorsed by ERMA New Zealand

[4] The *containment facility* refers to the area where the genetically modified trees are to be grown, and that is registered by MAF under the Biosecurity Act 1993.

2.4 Handling of genetically modified trees to be used in the field test shall ensure that no genetically modified trees are planted outside the field test site.

2.5 All plant material to be used in this field test shall be uniquely identified at all times.

2.6 A register of plants grown in the field test shall be maintained. The following records shall be made for each plant:

i. the identity of the plant and details of genetic modification;
ii. date of planting; and
iii. date and method of final disposal of plants.

2.7 Genetically modified trees shall be transferred from the plant house to the field test site in secure containment, which must include packaging in closed non-crushable boxes, and transport in an enclosed vehicle.

2.8 The maximum number of genetically modified plants in the field test shall not exceed 330 over the period of the approval.

2.9 All genetically modified trees in the field trial site shall be monitored weekly throughout the year by competent personnel familiar with the development of reproductive structures in *P. radiata* and *P.abies*. A log of each monitoring visit shall be maintained and made available for inspection.

2.10 The genetically modified *P. radiata* shall be destroyed and removed from the field test site at a maximum age of 6 years or at the initiation of reproductive structures, whichever occurs first. The genetically modified *P. abies* shall be destroyed and removed from the field test site at a maximum age of 8 years or at the initiation of reproductive structures, whichever occurs first. The age of the trees is calculated from when embryo is clearly identifiable and is transferred to germination medium in tissue culture.

2.11 The genetically modified trees shall be trimmed to maintain a maximum height of 3m.

[Control 2.12 was amended by the Authority under *s67A* on 28 May 2008, the revised control 2.12 appears at the end of these controls]

2.12 All genetically modified trees no longer required shall be cut down and any biological material derived from genetically modified trees no longer required shall be removed from the trial site and disposed of by incineration or autoclaving on the Forest Research site in accordance with the Section 7 of AS/NZS 2243.3:1995[3] and Section 4.4 of MAF/ERMA standard 155.04.09[3] *Containment Facilities for New Organisms (including GMOs) of plant species*.

2.13 The field test site shall be monitored for a further period of no less than 2 years after all the genetically modified trees have been removed, to detect any stump re-growth or seedling germination. If any re-growth appears within the first year the stumps shall be treated with a herbicide that will kill the tree stumps and the trial site monitored for further two years. This process shall be repeated until there is no re-growth for a minimum period of two years.

2.14 At the completion of the field trial, or in the event of premature ending of the trial, all genetically modified trees shall be destroyed in accordance with control 2.12 and the trial site shall be monitored in accordance with control 2.13.

3. To exclude unauthorised people from the facility:

3.1 A log of all persons accessing the field test containment facilities shall be maintained and be available for inspection by the facility Supervisor.

4. To exclude other organisms from the facility and to control unauthorised/undesirable and unwanted organisms within the facility:

4.1 A fence shall be constructed to restrict unauthorised access to the trial site.

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

5.1 The applicant shall comply with the requirements contained in the standards listed in controls 2.2 relating to the prevention of unintended release of the organism by experimenters working with the organism.

6. Inspection and monitoring requirements:

6.1 In case of unintended or accidental release or escape of genetically modified plants from the field trial, the applicant shall make all reasonable efforts to recover the plants and if they cannot be replanted in the trial site shall destroy them by incineration or autoclaving (see section 4.4 of MAF/ERMA New Zealand Standard 155.04.09[3] *Containment Facilities for New Organisms (including GMOs) of plant species*).

6.2 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.

7 Inspection and monitoring requirements:

7.1 The inspection and monitoring requirements for containment facilities shall be in compliance with the standards listed in control 2.1.

7.2 The applicant shall inform the facility Supervisor and ERMA New Zealand of the planting date of the trees in the field.

7.3 The containment manual shall be updated to implement the controls imposed by this decision according to the MAF/ERMA New Zealand Standard 155.04.09[3] *Containment Facilities for New Organisms (including GMOs) of plant species*. The manual shall specify the containment system within the plant house and the field test site. It shall also include the trial monitoring plan, including: a staff training plan, inspection plan and contingency plan. The contingency plan shall take into account any accidental release of plants outside the facilities; and fire or any other emergency.

7.4 A comprehensive report on the progress and the outcome of the field trial shall be provided to ERMA New Zealand by 15 December of each year of the field trial. This shall include information on:

a) the continuing viability of the project,
b) any incident of interference with the field trial (whether or not a containment breach occurred), the method of managing the incident and the outcome resulting from this incident
c) a plan of activities for the coming year, which may include future research on horizontal gene transfer
d) records of any precocious reproductive structures found

7.4.1 At the end of the field trial a comprehensive report on the outcome of the field trial shall be provided to ERMA New Zealand.

[Control 7.5 was amended by the Authority under *s67A* on 22 February 2001, the revised control 7.5 appears at the end of these controls]

7.5 The applicant shall establish an on-going liaison committee with Tuhourangi iwi, to enable local iwi 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.

Amendment to Control

The following amendment to the controls imposed on approvals GMF000028-31 of application GMF99005 was made by the Authority under *section 67A* of the Hazardous Substances and New Organisms Act 1996 on 22 February 2001.

The following control replaces Control 7.5 of decision dated 20 December 2000.

7. Inspection and monitoring requirements

7.5 The applicant shall establish an on-going liaison committee with representatives of

- Tuhourangi iwi, including Ngati Wahiao
- Ngāti Hurunga Te Rangi, Ngāti Taeotu, and Ngāti Kahu, hapu of Ngāti Whakaue
- Other subtribes of Te Arawa

to enable local iwi 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.

Amendment: April 2002

To correct standard numbers in the decision and to name the standards.
To include the full title of the Act in control 2.1
To add 'transport in an enclosed vehicle' to control 2.7
Add control 7.4.1 to require end of trial report

_____ Date: 8 April 2002

Jill White
Chair

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: 23 August 2007

Dr Kieran Elborough
Chair, GMO Standing Committee

Amendment: May 2008

The following control replaces Control 2.12 of decision dated 23 August 2007.

2.12 All living vegetative *Pinus radiata* and *Picea abies* material approval not retained for research purposes shall be killed by composting, incineration, autoclaving or another scientifically validated method.

_____ Date: 28 May 2008

Dr Kieran Elborough
Chair, GMO Standing Committee

Amendment: December 2009

The duration of the field test was extended for a further eight years. The approval will expire on 17 January 2018. The original two year post-harvest monitoring is to begin after this time.

_____ Date: 18 December 2009

Dr Kieran Elborough
Chair, GMO Standing Committee

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Appendix 1:**Genes, Promoters and Transformation events in GMF99005**

Gene	**Source**	**Expected function/characteristics**
*npt*II	*E.coli*	Resistance against aminoglycoside antibiotics, such as kanamycin and geneticin. Selection gene.
bla	*E.coli*	Resistance against ß-lactam antibiotics. Selection gene.
*uid*A	*E.coli*	Production of the enzyme ß-glucuronidase. Reporter gene.
bar	*Streptomyces hygroscopicus*	Productions of the enzyme phosphinothricin-acetyl-transferase (PAT). Herbicide resistance gene.
ALS(csr1-1) or HRA	*Arabidposis thaliana* and various other sources	Production of a modified acetolactate-synthase (ALS). Herbicide resistance gene.
Promoter	**Source**	**Characteristics**
CaMV 35S	Cauliflower mosaic virus	Constitutive promoter for expression of genes in dicotyledonous plants
Maize ubiquitin	*Zea mays*	Constitutive promoter for expression of genes in mainly monocotyledonous plant species
nos	*Agrobacterium tumefaciens*	Constitutive promoter for expression in plant tissue
lac	*E.coli*	Constitutive bacterial promoter used to express genes in *E.coli*
FMV and eFMV	Figwort mosaic virus	Tissue specific *P. radiata* promoter for a specific chalcone synthase gene
P. radiata polyubi	*P. radiata*	*P. radiata* promoter of a polyubiquitin gene. Expected to constitutively express genes in *P. radiata*

Transformation events

Pinus radiata bar
Pinus radiata ALS
Picea abies bar
Picea abies ALS

Appendix 2

Amendment to FRI Field trial approvals

At its recent meeting, the Authority amended the controls applying to the two FRI field trials approved in December 2000 (Application Numbers GMF99001 and GMF99005, approval codes GMF000032 to 39 and GMF000028 to 31).

The amendment was to replace control 7.5 in each approval with the following:

> *The applicant shall establish an on-going liaison committee with representatives of*
> - *Tuhourangi iwi, including Ngati Wahiao*
> - *Ngāti Hurunga Te Rangi, Ngāti Taeotu, and Ngāti Kahu, hapu of Ngāti Whakaue*
> - *Other subtribes of Te Arawa*
>
> *to enable local iwi 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.*

In the submission, hearing, and body of the decision, the representations were accepted as being on behalf of all the cited iwi and hapu, and the rewording of the control is intended to explicitly reflect this.