ENVIRONMENTAL RISK MANAGEMENT AUTHORITY DECISION

Amended under section 67A, 19 May 2017

18 November 2008

Application code:	GMR07001
Application type:	Import or Release a New Organism with controls under the Hazardous Substances and New Organisms (HSNO) Act 1996
Applicant:	The New Zealand Racing Board and New Zealand Equine Health Association
Purpose:	To gain approval to import for release genetically modified vaccines (Proteqflu and Proteqflu Te) to protect horses against Equine Influenza
Date application received:	13 June 2008
Hearing date:	7 October 2008
Decision date:	18 November 2008
Considered by:	Committee of the Authority

1 Summary of Decision

1.1.1 The application to conditionally release genetically modified (GM) Canarypox viruses in Table 1 below is **approved with controls** having been considered in accordance with the relevant provisions of the Hazardous Substances and New Organisms Act 1996 (the Act) and of the HSNO (Methodology) Order 1998 (the Methodology)

TABLE 1: Organism Description Summary

Host Organism: • Influenza A/equine-2/Ohio/03[H3N8]Canarypox virus (vCP2242); and • Influenza A/equine-2/Newmarket/2/93[H3N8]Canarypox virus (vCP1533).
Modifications: • Includes any variations to the Equine Influenza (EI) Haemagglutinin gene identified in new circulating strains but would not cover any changes in the ALVAC® cloning vector.

1.1.2 Major concerns raised by submitters were that:

- this would allow the first conditional release of GM organisms in New Zealand;
- no safety studies had been conducted with native birds;
- there was insufficient testing with other animals;
- alternative vaccines are available;
- it would be better to improve biosecurity measures; and
- there was a possibility of spread of vaccine virus through faeces and water.

1.1.3 The controls imposed on the approved organisms are set out in Appendix 1 to this decision. The controls provide for correct use, administration and secure storage of the organisms, and for the management of any risks such as spills.

1.1.4 In considering the application, all identified potentially significant adverse effects (risks and costs) of the organisms were assessed as negligible, taking into account the biological characteristics of the organisms contained in the vaccines Proteqflu and Proteqflu Te, and the controls required by this decision.

1.1.5 The principal benefits or positive effects were considered to be:

- that in the case of an outbreak equine animals present or imported into New Zealand are able to be immunised against Equine Influenza (EI);
- reduced costs to equine industry (general) as a result of protection (breeding, sales, rodeos, national and international competitions) and reduced costs to racing industry as a result of protection in the case of an outbreak; and
- enhancement of kaitiakitanga through the protection of a valued species.

1.1.6 The Committee considers the organisms for conditional release to meet the minimum standards in section 36 of the Act.

1.1.7 The Committee approves this application in accordance with section 38C. The Committee notes that since all risks and costs were **negligible**, taking into account the risk management measures imposed by the controls, clause 26 of the Methodology applies. The Committee concluded that the positive effects of the organisms outweigh the adverse effects.

2 Application Process

2.1 Legislative criteria for application

2.1.1 The application was lodged pursuant to section 38A of the Act. Unless otherwise stated, references to section numbers in this decision refer to sections of the Act. The decision was made in accordance with section 38C taking into account additional matters to be considered under sections 38C(2), 38C(3), 38D, and matters relevant to the purpose of the Act, as specified under Part II of the Act.

2.1.2 Consideration of the application followed the relevant provisions of the Methodology with particular regard to clauses 12 (dealing with assessment of risks) and 13 (dealing with assessment of costs and benefits). Unless otherwise stated, references to clauses in this decision refer to clauses of the Methodology.

2.2 Receipt of application

2.2.1 The application was formally received on 13 June 2008. Prior to formal receipt, the application was checked as required under section 38A and was considered to meet the information requirements for consideration. The Minister for the Environment was advised of the receipt of the application on 17 June 2008.

2.3 Decision-making Committee

2.3.1 In accordance with section 19(2)(b) and clause 43 of the First Schedule to the Act, the Environmental Risk Management Authority (the Authority) appointed a Committee to consider the application. The Committee comprised the following members of the Authority: Dr Kieran Elborough (Chair), Dr Max Suckling, and Dr Shaun Ogilvie.

2.4 Public notification

2.4.1 The application was publicly notified on 17 June 2008 in accordance with section 53(1)(ab). Notification was made in accordance with clause 7, and the method of public notification was determined by the Authority pursuant to section 53A. An alert notice was posted on the ERMA New Zealand website[1] and printed in *The Dominion Post*, *The New Zealand Herald*, *The Otago Daily Times* and *The Press* on 18 June 2008.

2.5 Submissions

2.5.1 Public submissions were open from 18 June 2008 until 29 July 2008. Submissions under section 54 were received from 29 submitters, of which 10 indicated that they wished to speak in support of their submissions. Seven submissions were spoken to at the hearing and the names of those who spoke are listed in Section 2.8.3 of this decision.

2.5.2 A list of all submitters can be found in Appendix 5a and 5b of the GMR07001 Evaluation and Review (E&R) report, available on the ERMA New Zealand website or on request from ERMA New Zealand.

2.6 Consultation with government departments

2.6.1 In accordance with section 53(4) and clause 5, and for the purpose of section 58(1)(c), various government departments and other agencies including district and regional councils were notified of the receipt of the application. Comments were received from the Department of Conservation (DOC) and the Ministry for Agriculture and Forestry Biosecurity New Zealand (MAF BNZ). A complete list of the government departments notified of this application can be found in Appendix 4 of the GMR07001 E&R report.

[1] http://www.ermanz.govt.nz/

2.7 Experts

2.7.1 Simon Harris of Harris Consulting provided an expert independent review (the Harris report) of the economic aspects of the application.

2.8 Hearing

2.8.1 A public hearing[2] was held in Wellington on 7 October 2008. Under section 59(5), the hearing was postponed to this date due to the unavailability of key personnel from the applicant team to attend the hearing.

2.8.2 The Committee selected Wellington as the venue for the hearing based on the location of the applicant. To enable submitters who were outside the region to be heard, the Committee also allowed telephone conferencing.

2.8.3 Presentations were made to the Committee at the hearing by the following persons:

For the applicant
New Zealand Racing Board/New Zealand Equine Health Association Board:

- Alan Galbraith — Legal Counsel
- Graeme Hansen — CEO New Zealand Racing Board
- Ivan Bridge — Equine vets
- Dr Paul Chambers — Massey University
- Greg O'Connor — CEO New Zealand Metropolitan Trotting Club
- Michael Martin — Thoroughbred Breeders Association
- Dennis Ryan — New Zealand Trainers Association
- James Peters — EO Australian Thoroughbred Breeders Association

Supported by Doug Balbraith, Legal Counsel

For submitters: Speaking on their own behalf and/or on behalf of other submitters:

- Jon Carapiet
- Claire Bleakley — GE Free New Zealand
- Claire Bleakley — on behalf of Michael Morris
- Steffan Browning — Soil and Health Association of New Zealand
- Jarad Bryant
- Simon Terry — Sustainability Council of New Zealand
- Susie Lees

[2] Section 60 of the Act and clause 2(2)(b) of the Methodology.

2.9 Summary of the Hearing Presentations

2.9.1 The following sections summarise the presentations from the applicant and submitters to the Committee. For a complete review of the hearing presentations, refer to Appendix 2.

The applicant

2.9.2 The Committee heard from eight members representing the New Zealand Racing Board and New Zealand Equine Health Association. Alan Galbraith, Legal Council acknowledged that the applicant accepts the recommendations in Appendix 1 of the E&R report and any updates of the vaccines as mentioned on page 4 of E&R report. He also stated that the application is not only a benefit to racing industry but to equine industry as well.

2.9.3 Graeme Hansen, CEO New Zealand Racing Board gave an introduction of the topics that would be presented during the hearing by the applicant such as the:

- objectives of the New Zealand Racing Board Racing;
- objectives of the New Zealand Equine Health Association;
- size and Scope of the New Zealand Racing Industry;
- how the New Zealand Racing Board funds the industry;
- why use Proteqflu?
- the impact of an EI outbreak in New Zealand;
- the importance of a rapid response; and
- the EI outbreak in Australia.

Submitters opposing the application

2.9.4 Among the issues raised by submitters at the hearing were that:

- this is the first release of a genetically modified organism (GMO) in New Zealand;
- there are have not been any safety studies with native birds conducted;
- there has been insufficient testing with other animals;
- alternative vaccines are available;
- there are liability issues that have not been addressed;
- it would be better to focus on improvement of biosecurity measures to prevent an outbreak of EI;
- the benefits are debateable; and
- there are concerns that the vaccine virus might spread through faeces and water.

2.9.5 The Committee notes that these concerns were addressed:

- the first release of a GMO in New Zealand is not a relevant consideration;
- native birds (sections 3.9.9 – 2.9.12 in this decision);
- testing of animals was sufficient (Section 6.1 in the E&R report);
- alternative vaccines are available (Sections 8.16.33 and 10.3 in the E&R report);
- liability issues are not a relevant consideration;
- the vaccines would serve as an important biosecurity tool;
- the Agency agreed that the market economy benefits were marginal (Section 9.6.17 in the E&R report); and
- environmental testing of the ALVAC® backbone has been conducted (Section 8.5.13 of E&R report).

2.9.6 Many submitters were concerned that Table 4 in Section 9.6.12 of the E&R report was not the same as the Table 1 in the Harris report (Appendix 10b, page 134 of the E&R report). The Committee notes that Table 4 is taken from the NZIER report, not from the Harris report.

2.9.7 Some submitters expressed their frustration with the process and in particular raised concerns that they do not feel that they were being listened to. The Committee wishes to assure those submitters that their concerns were listened to and that the Committee has taken full account of the issues raised.

Additional information provided to the Committee

2.9.8 Susie Lees sent an e-mail to ERMA New Zealand on 3 October 2008 with additional information, three scientific articles for the Decision-making committee to consider. She also mentioned this during her submission at the hearing. The Committee notes that:

- Theil et al, 2005 was used as reference in the E&R report, Section 6.1.15 to review the potential for recombination. The Committee noted that recombination between co-infecting Canarypox-like viruses may contribute to the diversity observed between avipoxviruses in the Galápagos Islands;
- Jones, 2007 provides no new information since the E&R report (Section 9.2.20) states that the GMO vaccines have not been tested in New Zealand native bird populations.
- Stanley and Mackenzie, 1983 reports new avian Influenza A strains and identification of quokkapox in small wallabies. The E&R report, Section 5.3.5 states that new Influenza A strains appear over time due to antigenic drift and antigenic shift. Quokkapox are not relevant to the application GMR07001 as there are many pox viruses that are host specific reported in nature.

2.9.9 Te Rūnanga o Ngāi Tahu provided ERMA New Zealand with a document that assesses the current application taking into account Ngāi Tahu values and interests informed by kaitiakitanga and rangatiratanga. This document was available to the Authority during the decision-making process and is available upon request from ERMA New Zealand.

Conclusion

2.9.10 The Committee acknowledges the submitters who made a considerable effort and investment to be involved in the hearing and thanks them all for their attendance and involvement. The Committee appreciates the submitter's contributions which are a valuable component of the decision-making process.

2.10 Information available for the consideration

2.10.1 The information available for consideration by the Committee comprised:

- Application GMR07001 (Form NORC);
- Evaluation and Review (E&R) report;
- Te Rūnanga o Ngāi Tahu report;
- Māori Reference Group report;
- Public submissions; and
- Information presented at the hearing.

3 Consideration

3.1 Sequence of the consideration

3.1.1 The consideration of the application began at the conclusion of the hearing on 7 October 2008 and continued on 10 October 2008.

3.1.2 The application was determined in accordance with section 38C of the Act. In making this decision the Authority has applied the relevant sections of the Act and followed the relevant provisions of the Methodology.

3.1.3 In accordance with clause 8, the Committee considered the information provided from the sources listed in Section 2.10 above. The Committee decided that there was sufficient information for consideration in terms of section 38A(2) of the Act and clauses 8, 15, 16, 20, 22 and 23 of the Methodology.

3.1.4 The Committee looked sequentially at identification, assessment and the combined evaluation of risks, and of costs and benefits. Identification of potential risks and costs took into account the matters in clauses 9 and 10. Interposed with this were the identification of controls that might be used to manage the risks. These controls considered (but not be limited to) those listed in section 38D(1) and were assessed in relation to the identified risks and those risks identified as significant (clause 12). The Committee considered the likely effectiveness of the identified controls, and extent and impact of the controls to mitigate risks in accordance with section 38C(3) and section 38D(2) of the Act.

3.1.5 Section 38C(2) and (3) of the Act require that the Authority takes account of the ability of the organism to establish a self sustaining population and the ease of recovery or eradication should it establish an undesirable self-sustaining population.

3.1.6 Taking into account the proposed controls, the Committee determined whether the organism is likely to meet the minimum standards (specified in section 36 of the Act).

3.1.7 The Committee considered that with controls in place all adverse effects (risks and costs) were negligible and therefore the decision could be made in accordance with clause 26.

3.1.8 Finally, the Committee concluded that the combined positive effects of the organisms outweighed the combined adverse effects (risks and costs).

3.2 The application

3.2.1 The New Zealand Equine Health Association and the New Zealand Racing Board are seeking approval to import for conditional release the GM vaccines Proteqflu and Proteqflu Te under section 38A of the Act.

3.2.2 The purpose of the application is to import for conditional release GM vaccines (Proteqflu and Proteqflu Te) to protect horses against EI.

3.2.3 This application arose as a result of the August 2007 outbreak of EI in Australia. This outbreak occurred following the importation to Australia of infected horses from Japan and a failure to contain the disease in quarantine facilities.

3.2.4 The New Zealand equine industry has lodged this application in order to minimise the economic and social impacts of any potential EI outbreak in New Zealand. The applicant considers this to be a pro-active step by the industry to be prepared in the event of an outbreak. The applicant notes that, if successful, this application will also enable the vaccination of export horses travelling to areas in which vaccination with Proteqflu is a prerequisite for entry, or to countries where EI is endemic.

3.3 Identification of the potentially significant effects of the organisms

3.3.1 The Committee identified adverse and positive in accordance with clauses 9 and 10.

3.3.2 The Committee evaluated all effects identified by the applicant, public submissions, and effects identified by the Agency in their E&R report (Section 8, Table 2) as well as further effects identified during the public hearing. Only those effects identified as potentially signficant by the Committee are discussed below.

3.3.3 The Committee categorised the potential effects of this application in relation to the following areas of impact: the environment, human health and safety, the relationship of Māori to the environment, Treaty of Waitangi principles, society and community, and market economy in accordance with sections 5, 6 and 8 and clause 9.

The environment

Adverse effects

3.3.4 The Committee identified the following potentially significant adverse effects on the environment:

- development of novel viruses with altered pathogenicity, or altered host range that spread beyond the vaccinated horse; and
- increased mortality rates of native bird populations in New Zealand due to outbreak of Canarypox virus.

Beneficial effects

3.3.5 The Committee identified the following potentially significant beneficial effects on the environment:

- equine animals present or imported into New Zealand are immunized against EI and the likelihood of the disease outbreak is reduced.

Human health and safety

Adverse effects

3.3.6 The Committee identified the following potentially significant adverse effects on human health and safety:

- recombination of Canarypox virus and Molluscum contagiosum virus to cause human disease.

Beneficial effects

3.3.7 The Committee did not identify any potentially significant beneficial effects on human health and safety.

Effects on the relationship of Māori to the environment

Adverse effects

3.3.8 The Committee identified the following potentially significant adverse effects on the relationship of Māori to the environment:

- adverse impact on the role of Māori as kaitiaki through the potential compromise of native bird species and related traditional Māori values and practices.

Beneficial effects

3.3.9 The Committee identified the following potentially significant adverse effects on the relationship of Māori to the environment:

- enhancement of kaitiakitanga through the protection of a valued species; and
- improved economic stability for Māori working in the horse industry or who are auxiliary suppliers.

Effects on society and community

Adverse effects

3.3.10 The Committee identified no potentially significant adverse effects on society and community.

Beneficial effects

3.3.11 The Committee identified no potentially significant beneficial effects on society and community.

Effects on the market economy

Adverse effects

3.3.12 The Committee did not identify any potentially significant adverse effects on the market economy.

Beneficial effects

3.3.13 The Committee identified the following potentially significant beneficial effects on the market economy:

- reduced costs to equine industry (general) as a result of protection (breeding, sales, rodeos, national and international competitions) and reduced costs to racing industry as a result of protection.
- equine animals exported from New Zealand are immunized against EI to achieve market access (where required).

3.4 Additional effects identified at the hearing

3.4.1 Ivan Bridge mentioned the ease of using Proteqflu over Flu Avert® I.N. Based on this submission, the Committee noted the ease of administering Proteqflu or Proteqflu Te to horses compared to Flu Avert® I.N., the occupational safety and health risk with nasal administration and the number of horses that can be vaccinated faster. Therefore, there would be a larger positive effect than identified in the E&R report because the vaccination rate is more successful.

3.4.2 Those effects considered potentially significant were assessed in further detail in Section 9 in the E&R report and are considered in more detail in Section 3.8 of this decision.

3.5 Approved organism description

3.5.1 The approved organism description is listed in Table 1, paragraph 1.1.1 of this decision.

3.6 Controls and their adequacy

3.6.1 The Committee considered the controls that the Authority may impose on this conditional release approval under section 38D.

3.6.2 The Committee considered the controls suggested by the applicant, submitters, the Agency, DOC and MAF BNZ.

3.6.3 The Committee notes that under the Agricultural Compounds and Veterinary Medicines Act 1997 (ACVM), Proteqflu and Proteqflu Te will be assessed during the ACVM registration process and that controls addressing the requirements of the ACVM Act will be applied in addition to HSNO Act controls.

3.6.4 The Committee accepted controls 1, 2 and 5 as proposed by the Agency in Appendix 1 of the E&R report and that they are effective in meeting their objectives according to section 38C(3)(a) and (b). Specific objective addressed by the controls include:

- vaccine administration, to ensure the vaccine is used appropriately and not misused;
- auditing, to ensure compliance with the controls can be checked; and
- disposal, to limit exposure to the vaccines.

3.6.5 The Committee considered the likely effectiveness of the identified controls, and the extent and impact and imposed six controls which are listed in Appendix 1.

3.7 Duration of conditional release approval

3.7.1 The Committee is satisfied that there is no need for an expiry date for this approval under section 38E of the Act based on control 6 (Appendix 1) which limits the use of the vaccine.

3.8 Ability of organisms to establish an undesirable self-sustaining population

3.8.1 In accordance with section 38C(2)(b) of the Act, the Committee considered the ability of these GM ALVAC®based Canarypox vaccines to form a self-sustaining population. In the case of a virus, the self-sustaining population means the ability to survive indefinitely by replicating and spreading from host to host.

3.8.2 The Committee noted that the ALVAC®based Canarypox vaccines do not replicate or spread in mammalian hosts, and have been used internationally since 2003.

3.8.3 The Committee concluded that it is **highly improbable** that the ALVAC®based Canarypox vaccines could form a self-sustaining population when taking into account the controls and the biological characteristics of the organisms.

3.8.4 The Committee noted, in accordance section 38C(2)(c) and 38C(3)(c), that if the ALVAC®based Canarypox vaccines did form an undesirable self-sustaining population, the organisms would not cause disease in canaries and they would over come infection.

3.9 Assessment of the potentially significant effects of the organism

3.9.1 The adverse (risks and costs) and positive effects assessed below are those identified as potentially significant, having regard for those matters set out in clauses 9 and 10 and sections 5 and 6. Risks were considered in terms of the requirements of clause 12, including the assessment of the magnitude of the consequences and probabilities of their occurrence, the nature and impact of uncertainty and the impact of risk management. The evidence available to the Committee was evaluated in accordance with clause 25.

3.9.2 For each effect the Committee addressed the following considerations, as set out in the Methodology, as far as is reasonably practicable:

- The nature of the adverse effects (clause 12(a));
- The probability of occurrence and the magnitude of each adverse effect (clause 12(b));
- The risk assessed as a combination of the likelihood of occurrence and the magnitude of the adverse effect (clause 12(c));
- The benefits were considered in terms of the requirements of clause 13;
- The options and proposals for managing the risks identified (clause 12(d)); and
- The uncertainty bounds on the estimates (clause 12(e)) and how uncertainty affects the assessment of the risk (clause 25 - scientific and technical uncertainty, clause 29 - materiality of uncertainty, and clause 30 - need for caution where not resolved).

3.9.3 Table 2 summarises the five significant positive effects discussed below.

TABLE 2: Summary of significant effects – all effects other than the market benefit of vaccinating horse for export are assessed on the basis that an incursion has occurred. This impacts on the likelihood of the effect occurring.

Description	Magnitude	Likelihood	Effect level	Uncertainty and Comments
Equine animals present or imported into New Zealand are immunised against EI and the likelihood of the disease outbreak is reduced	Moderate	Likely	E	Uncertainty of arrival of the EI virus to New Zealand.
Enhancement of kaitiakitanga through the protection of a valued species	Moderate	Likely	E	No comment.
Improved economic stability for Māori working in the horse industry or who are auxiliary suppliers	Minor	Likely	E	Uncertainty about the number of Māori working in the horse industry or who are auxiliary suppliers.
Reduced costs to equine industry (general) as a result of protection (breeding, sales, rodeos, national and international competitions) and reduced costs to racing industry as a result of protection	Moderate	Unlikely	E	Uncertainty about the size of the effect. While this may be an overestimate of the positive effect since the contribution of Proteqflu and Proteqflu Te cannot be disaggregated from other control measures, other potentially significant positive effects on the market economy have been omitted because of lack of information.
Equine animals exported from New Zealand are immunised against EI to achieve market access (where required)	Moderate	Likely	E	This measure is not currently required but is expected to become mandatory in some countries.

The environment

Adverse effects

Development of novel viruses with altered pathogenicity, or altered host range that spread beyond the vaccinated horse

3.9.4 The Committee considered whether the conditional release of a vaccine containing live GM viruses could result in the development of novel viruses with altered pathogenicity, vector specificity or host range that spread beyond the vaccinated horse and have a potentially significant adverse effect on the environment.

3.9.5 For this effect to arise the vaccine must be improperly used or disposed of and that recombination between the vaccine virus strains and another virus would be required. These pathways were assessed as being **highly improbable** based on the biological characteristics of the organism and the suggested controls proposed on the use and disposal of this vaccine (Appendix 1, controls 1 and 5).

3.9.6 A number of submitters have raised concerns regarding the ability of the vaccine to recombine with another virus leading to the formation of a pathogenic new virus.

3.9.7 The applicant noted that the vaccine organism does not replicate or survive in mammalian cells and therefore does not pose a risk to the environment or public health. This was demonstrated by clinical studies that tested the genetic and biological stability of the vaccine organism (Paoletti, 1994).

3.9.8 The Committee concludes that the magnitude of this adverse effect is **minimal** and that it is **highly improbable** that this effect will occur. Thus, the level of effect is **A**. The Committee concluded this effect is **negligible**.

Increased mortality rates of native bird populations in New Zealand due to outbreak of Canarypox virus

3.9.9 A number of submitters raised concerns that the virus would have an effect on native birds. The Committee considered whether the conditional release of a vaccine containing live GM viruses could result in the spread of the Canarypox virus to native bird populations in New Zealand, resulting in high mortality and therefore having a potentially significant adverse effect on the environment.

3.9.10 The Committee notes that the ALVAC® strain of Canarypox virus has been attenuated to the level that it has lost the ability to produce infectious progeny and therefore does not cause disease in canaries (Plotkin et al, 1995).

3.9.11 The Committee acknowledge there are no reports showing the safety of the GM vaccine viruses present in Proteqflu or Proteqflu Te in native New Zealand birds.

3.9.12 Based on the biological characteristics of the organism and the proposed controls, the Committee considered that the magnitude of the effect of increased mortality rates of native bird populations due to outbreak of Canarypox virus would be **minimal** and that it is **highly improbable** that this effect would occur. Thus, the level of effect is **A**. The Committee considered this effect is **negligible**.

Positive effects

Equine animals present or imported into New Zealand are immunized against EI and the likelihood of the disease outbreak is reduced

3.9.13 The Committee considered whether the conditional release of a vaccine containing live GM viruses could prevent EI in New Zealand and have a potentially significant benefit on the environment.

3.9.14 Proteqflu or Proteqflu Te have been approved by the European Medicines Agency (EMEA) since 2003 as vaccines to prevent EI in horses, donkeys and zebras. Clinical trials by Merial indicate after vaccination with Proteqflu or Proteqflu Te, the susceptibility to EI infection of at-risk horses, severity of clinical signs and the level of viral shedding is significantly reduced. The vaccines provided rapid immunity (14 days after primary vaccination course) compared to alternative vaccines available on the current market, thus improving the welfare of the animal.

3.9.15 The Committee noted that EI is highly infectious and vaccination would provide a valuable biosecurity tool in the face of an EI outbreak. However, there is uncertainty with the probability that the EI virus will arrive in New Zealand.

3.9.16 The Committee concluded that the conditional release is important in terms of maintaining the EI freedom status of New Zealand, for imports and exports and during an outbreak in New Zealand. The Committee considered that the magnitude of this positive effect is **moderate** and that it is **likely** that this effect will occur. Thus, the level of effect is **E**. The Committee considered this effect is **non-negligible**.

Human health and safety

Adverse effects

Recombination of Canarypox virus and Molluscum contagiosum virus to cause human disease

3.9.17 Proteqflu and Proteqflu Te have not been administered to human subjects; however, the safety of the Canarypox vector (ALVAC®) present in other vaccines has been investigated in human subjects or cell lines to show that live ALVAC® does not produce disease in healthy subjects or immunosuppressed patients. This was also highlighted by the applicant during the hearing.

3.9.18 The Committee considered the magnitude that the conditional release of a vaccine containing live GM viruses to recombine with Molluscum contagiosum virus to be **minimal**, and that it is **improbable** that this effect would occur considering the proposed controls (Appendix 1). Thus, the level of effect is **B.** The Committee considered this effect is **negligible**.

3.9.19 With respect to the potential human health and safety adverse effects, the Committee recognised that there would be an effect on psychological and emotional wellbeing from both the horse industry and the GM free groups if the organism was approved or not.

3.9.20 With respect to the potential human health and safety positive effects, the reduction in emotional stress, the Committee recognised that there would be an effect on both the horse industry and the GM free groups if the organism was approved or not.

The relationship of Māori to the environment

3.9.21 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) and in clause 9(c)(iv).

Adverse effects

Adverse impact on the role of Māori as kaitiaki through the potential compromise of native bird species and related traditional Māori values and practices

3.9.22 Susie Lees raised concerns that the approval of the vaccine will have an effect on Māori with relation to gambling. The Committee stated that gambling issues were not effects of the organism and that there is no difference if the vaccine is GM or not regarding this effect.

3.9.23 The Committee confirmed that the issues raised from the Māori Reference Group report have been addressed in the E&R report.

3.9.24 The role of Māori as kaitiaki has been formally recognised as guardians and/or stewards of New Zealand's natural resources. The conditional release of the organisms in the vaccines Proteqflu and Proteqflu Te could compromise taonga native bird species and the traditional values and practices associated with those species if the Canarypox virus spreads. However, based on the biological characteristics of the organisms and the proposed controls, the Committee considered that the magnitude of the effect to the mauri, mana and tapu and the role of Māori as kaitiaki in their protection to be **minimal** and that it is **highly improbable** that this effect would occur. In addition, having regarded the information available, the Committee considered the magnitude of the impact of such an occurrence to be **minimal**. Thus, the level of effect is **A**. The Committee considered this effect to be **negligible**.

Positive effects

Enhancement of kaitiakitanga through the protection of a valued species

3.9.25 Kaitiakitanga encompasses the intergenerational protection and enhancement of taonga, both physically and spiritually. In terms of the latter, the role of Māori as kaitiaki includes the protection and enhancement of the mauri, mana and tapu of taonga. This extends not just to people, land, waterways, tikanga and mātauranga Māori, but also to valued flora and fauna or ngā taonga tuku iho (ERMA New Zealand, 2004).

3.9.26 The Committee acknowledge that horses have been and continue to be considered taonga by many Māori. They have served as an important source of transport for Māori for several generations and are still used in a number of particularly rural regions for both transport and work.

3.9.27 Having considered the information, the Committee acknowledged that the enhancement of kaitiakitanga through the protection of a valued species from the conditional release of a vaccine containing live GM viruses to have a **moderate** magnitude and it is **likely** to occur. Thus, the level of effect is **E.** The Committee considered this effect to be **non-negligible**.

Improved economic stability for Māori working in the horse industry or who are auxiliary suppliers

3.9.28 Although there was insufficient data on the statistics and nature of Māori involvement in the equine industry, the Committee considered there were enough examples in the E&R report (Sections 9.5.8 – 9.5.9) which show the importance of the industry to Māori communities.

3.9.29 Having considered this information, the Committee concluded the magnitude of this effect was **minor** from the availability of Proteqflu and Proteqflu Te and that it is **likely** that this effect would occur. Thus, the level of positive effect is **E**. The Committee considered this effect to be **non-negligible**.

The market economy

3.9.30 The Committee noted it is not possible to determine how much of the benefit to the market economy from amelioration of the effects of an EI incursion could be apportioned to these particular vaccines. However, the Committee is of the view that there will be some benefits as assessed below.

3.9.31 The Committee notes Jon Carapiet's submission regarding the Agency's assessment of adverse effects on the market economy and acknowledges that the Ministry for the Environment report was produced in 2001. However, this is the only information available at present.

Positive effects

Reduced costs to equine industry (general) as a result of protection (breeding, sales, rodeos, national and international competitions) and reduced costs to racing industry as a result of protection

3.9.32 The Committee discussed the range of magnitude and likelihood with Table 5 in the E&R report. The Committee noted that if the application is approved with controls for use in only an emergency response situation or for export of horses then the lower bound for this effect does not apply as it relates to the scenarios where the vaccines are not used in managing an EI outbreak.

3.9.33 The Committee noted that there is uncertainty about the size of the positive effect and concluded that the magnitude of this effect was **moderate** and that it is **unlikely** that this effect would occur. Thus, the level of effect is **E**. The Committee considered this effect to be **non-negligible**. The Committee considered that this effect will only occur in the event of an EI incursion or outbreak.

Equine animals exported from New Zealand are immunised against Equine Influenza to achieve market access (where required)

3.9.34 Based on information provided at the hearing and during the consideration, the Committee concluded that the vaccination of equine animals exported from New Zealand where market access requires the use of Proteqflu and Proteqflu Te vaccines was an additional positive effect of the organisms.

3.9.35 The Committee considered that based on information provided by Michael Martin for the applicant that the total export market is $145 m per year for horses, that magnitude of this effect was **minor** and that it is **likely** to occur since it is anticipated that some international markets will demand the horses be vaccinated with Proteqflu or Proteqflu Te upon entry. The effect level is **E**.

3.10 Overall evaluation of risks, costs and benefits

Combining and weighing of risks, costs and benefits

3.10.1 The following overall evaluation of risks and costs (incorporating adverse effects) and benefits (incorporating beneficial or positive effects) was carried out having regard to clauses 22 and 34, and in accordance with the tests in clause 26 and section 38C. Clause 26 is the appropriate reference for making the decision since all identified potentially significant risks have been assessed as being **negligible**.

3.10.2 Risks and costs considered but found to be **negligible** were those associated with effects on the environment, effects on human health and safety, and the relationships of Māori to the environment. In making these assessments the Committee considered both the impact of controls and the effects of the GM Canarypox viruses to form a self-sustaining population. In aggregate, all risks were considered to be **negligible**.

3.10.3 Table 2 summarises the five significant positive effects. It describes the magnitude of the effect, the likelihood of that magnitude of effect occurring, the uncertainly associated with the effect and the associated level of effect determined by combining the magnitude and the likelihood. The Committee assessed these benefits as **non-negligible**.

3.10.4 Consequently, the Committee determined that the **positive effects of the organisms outweigh the adverse effects of the organisms**.

3.10.5 Finally, the Committee decided that the approval applies to two situations:

1. To the export of equine animals where it is a requirement of the importing country; and
2. For use to manage an outbreak of EI.

3.11 Decision

3.11.1 Pursuant to section 38C(1) of the Act, the Committee may approve the application if:

- the organisms are likely to meet the minimum standards set out in section 36 (taking controls into account); and
- there is sufficient information available to assess the adverse effects of the organisms; and
- the positive effects of the organisms outweigh the adverse effects of the organisms and any inseparable organism.

3.11.2 The Committee is satisfied that the organisms will meet the minimum standards set out in section 36, based on the information presented in the preceding risk assessment, and the proposed controls, that the organisms are not likely to:

- cause any significant displacement of any native species within its natural habitat;
- cause any significant deterioration of natural habitats;
- cause any significant adverse effects on human health and safety;
- cause any significant adverse effect to New Zealand's inherent genetic diversity; or
- cause disease, be parasitic, or become a vector for human, animal, or plant disease (unless that is the purpose of the release).

3.11.3 The Committee was satisfied that there was sufficient information to assess the adverse effects of the organisms.

3.11.4 The Committee was satisfied that the duration of the conditional release approval has no expiry date.

3.11.5 Consequently, the Committee determined that the positive effects of the organisms outweigh the adverse effects of the organisms and thus the application for conditional release of Proteqflu and Proteqflu Te is approved with controls.

3.11.6 In reaching this decision, the Committee has applied the following criteria in the Methodology:

- clause 9 – equivalent of sections 5, 6 and 8;
- clause 10 – equivalent of sections 36 and 38C(2);
- clause 12 – evaluation of assessment of risks;
- clause 13 – evaluation of assessment of costs and benefits;
- clause 15 and 16 – information from submissions;
- clause 17, 18 and 19 – information from experts;
- clause 20 – information produced from other bodies;
- clause 21 – the decision accords with the requirements of the Act and regulations;
- clause 22 – the evaluation of risks, costs and benefits – relevant considerations;
- clause 23 – obtaining further information;
- clause 24 – the use of recognised risk identification, assessment, evaluation and management techniques;
- clause 25 – the evaluation of risks;
- clause 26 – all risks are negligible and the benefits outweigh the costs
- clause 29 and 32 – considering uncertainty;
- clause 33 – the risk characteristics; and
- clause 34 – the aggregation and comparison of risks, costs and benefits.

3.11.7 The application for importation for conditional release of GM Canarypox viruses (**listed in Table 1**) is thus **approved with the controls** set out in **Appendix 1.**

_____ 18 November 2008

Dr Kieran Elborough Date:

Chair, Decision-making Committee

Approval codes (BCH numbers): GMR000001 – 02 (47482 – 83)

Amendment: May 2017
Amended Control 6 to make a minor in effect change to remove the restriction on use from export only to countries that require Proteqflu or Proteqflu Te, to countries that require vaccinations against equine influenza, but do not specify a requirement for a particular vaccine.

Amended Controls 1, 2, 3, 4 and 5 to make minor in effect changes to update the names of the regulatory and compliance agencies to their current names (MAF BNZ to MPI and ERMA New Zealand to EPA)

19 May 2017
Date:

Dr Kevin Thompson
Chair, Decision Making Committee, Environmental Protection Authority

Approval numbers and BCH numbers for Organisms in Application GMR07001

Approval Code	Organism	BCH number
GMR000001	Genetically modified equine influenza vaccine Proteqflu Te (GMR07001)	47482
GMR000002	Genetically modified equine influenza vaccine Proteqflu(GMR07001)	47483

3.12 References

ERMA New Zealand 2004. *Incorporating Māori Perspectives in Part V Decision Making ER-PR-01-02 11/04*. ERMA New Zealand, Wellington, New Zealand. http://www.ermanz.govt.nz/resources/publications/pdfs/ER-PR-01-02.pdf Retrieved June 2008.

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Thiel, T, Whiteman, NK, Tirape, A, Baquero, MI, Cedeno, V, Walsh, T, Uzcategui, GJ, Parker, PG 2005. Characterization of Canarypox-like viruses infecting endemic birds in the Galapagos Islands. *Journal of Wildlife Diseases* 41: 342-353.

Appendix 1: Controls

In order to provide for the matters detailed in Section 38D of the Act, the approved organisms are subject to the controls set out below.

1. **Control 1**: Any person using these vaccines must ensure that these vaccines are only administered to equine animals such as horses, donkeys, and zebras, and only by a veterinarian who has been trained, specifically on the controls placed on the use of this vaccine by MPI.
2. **Control 2**: Any registrant of the vaccine must maintain records of vaccine stocks and must make those records available to MPI for auditing.
3. **Control 3**: Any MPI-approved person storing these vaccines must ensure that the vaccines are stored in a secure location and ensure that the expired vaccines are disposed of as hazardous waste. Also, that person must ensure that a record is kept of all the vaccine stock coming into and going out of such a location and must make those records available to MPI for audit.
4. **Control 4**: Any person storing, transporting or using these vaccines must ensure that any spills including storage facility and one-off spills of the vaccine are disinfected by treating with the best available and most appropriate disinfectant (eg, 70% ethanol). In addition, any spills should be recorded and notified to MPI and to the EPA.
5. **Control 5**: Any person using these vaccines must ensure that contaminated waste from the genetically modified vaccines (including syringes, needles, disposable overalls, gloves, masks and any other material exposed to the genetically modified product) must be collected, treated and disposed of as hazardous waste. Disposal of expired vaccines must be in accord with the requirements of MAF/ERMA New Zealand Standard *Facilities for Microorganisms and Cell Cultures: 2007a*[3].
6. **Control 6**: The vaccines can only be used on equine animals for export to a country that requires vaccination for Equine influenza, or in an Equine Influenza outbreak in New Zealand as defined by MPI.

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

Appendix 2: Hearing presentations

The applicant

3.12.1 Dr Ivan Bridge, Equine Vets Ltd, described EI in terms of effect, transmission, treatment, recovery and outlined the following advantages of Proteqflu use compared to the dead vaccine in an outbreak situation. Proteqflu:

- gives much faster onset of immunity, 14 days;
- provides immunity to foals which still have colostral derived antibodies. With dead vaccine even minute quantities of maternally derived antibodies can interfere with successful vaccination of foals born to immunised mares;
- Proteq vaccinated horses can be differentiated from horses that have been naturally infected; and
- can be manufactured in large quantities very rapidly.

3.12.2 In comparison, Dr Bridge also discussed the alternative vaccine, Flu Avert® I.N, a live modified virus, which has been approved for use in New Zealand and noted that it:

- is administered intranasal and is more difficult to administer to large number of horses;
- vaccinates against narrow strains of EI virus;
- is not widely used internationally in combating EI and is only used in the USA;
- does not allow the use of the DIVA test to differentiate vaccinated horses against naturally infected horses; and
- would interfere with the PCR test, which is our most reliable to confirm active EI.

3.12.3 Dr Ivan Bridge concluded that the availability of ProteqFlu vaccine, which would be used under the direction of MAF BNZ, would be a critical tool in the efficient and rapid control of any EI incursion.

3.12.4 Dr Paul Chambers, Massey University explained the regulatory process for approval of Proteqflu in the European Union including quality of the vaccine in terms of consistency; safety (toxicology, clinical trials); efficacy on animals and humans; and risk assessment. He concluded that the European Public Assessment reported that product is safe at very high doses in horse, the live viruses contained in the vaccine do not spread, there is no environmental risk, and the benefit to risk ratio for ProteqFlu is favourable. The difference to New Zealand regulation is that the social and cultural benefits and risks are not considered in the European process.

3.12.5 Greg O'Connor, CEO New Zealand Metropolitan Trotting Club, Christchurch presented the cost and financial impact of an EI outbreak on Harness Racing in Canterbury. He concluded that an outbreak of EI would decimate harness racing in Canterbury for 3 to 6 months, its financial and human impact would directly affect almost 6,000 people and the indirect financial impact on associated industries would be much wider.

3.12.6 Greg O'Connor also stated that if an EI outbreak occurred in the spring, the effect on breeding and New Zealand Cup Week would be devastating, and there would be a follow on human and financial costs left by EI with lower foal numbers for racing in the future plus the cost of marketing the restarting of racing.

3.12.7 Michael Martin, CEO, Thoroughbred Breeders Association presented an overview of the Thoroughbred Breeders Association and discussed the size and scope of the Thoroughbred industry. He also provided New Zealand Broodmares and New Zealand Racing statistics.

3.12.8 Dennis Ryan, New Zealand Trainers Association presented an overview of the New Zealand Trainers Association, an outline of Racehorse Training Infrastructure, as well as a case study of a Trans-Tasman Trainer and the economic contribution of trainers, horse-breakers and pre-trainers and those in the business of grazing animals. He also presented the cost breakdown of running a typical training stable in New Zealand ($97,217). This case study highlighted the massive contribution that trainers make to the regional and national economy, and demonstrated that a single 40-horse operation in a year has an annual expenditure exceeding $1.1 million and income estimated at $1.3 million.

3.12.9 James Peters, EO Australian Thoroughbred Breeders Association reviewed the 2007 EI outbreak in Australia. He concluded that:

- it is important to provide faster immunity in order to minimise the short and long-term impacts of the EI virus on the economy, local businesses and the equine and racing communities;
- if an EI outbreak was to occur in New Zealand, without adequate vaccination measures in place, it would have a detrimental impact on New Zealand racing and breeding industry as was evident during the Australian EI crisis;
- an EI outbreak of the same magnitude as the 2007 Australian outbreak in New Zealand would result in a nationwide shut down of all horse related activities;
- in the case of an outbreak there would be an immediate suspension on all horse movement both domestic and international. This would severely compromise the New Zealand racing and breeding industry and the export sale of horses; and
- an outbreak would cause major disruptions to the earning streams of industry participants. It would also result in a reduction in tax revenues paid to the New Zealand government.

Submitters opposing the application

3.12.10 Several submitters to the hearing – Jon Carapiet, Claire Bleakley (GE Free New Zealand), Michael Morris, Steffan Browning (Soil and Health Association of New Zealand), Jarad Bryant, Simon Terry, Susie Lees, and Simon Terry expressed concerns about allowing the first conditional release of GM organisms in New Zealand.

3.12.11 Jon Carapiet criticised the Agency's assessment of the adverse effects on the market economy in Section 8.19 of the E& R report. He expressed the view that some of the references were out-of-date or not creditable.

3.12.12 Claire Bleakley requested clarification from the applicant; as to when vaccination occured on the graph presented by Grahame Hansen (slide 12). He responded that it was week 5. This was also followed with the question 'do you know the number of properties not involved?' James Peters responded that an audit will take place.

3.12.13 Claire Bleakley requested clarification from the applicant with regards to the antibody response following the second vaccination at day 25 with Proteqflu. Dr Chambers response was that antibodies are generated at the first injection with a booster at day 35 and peak antibodies measured at day 49. Claire Beakley then asked if you can compare the vaccines with non GM vaccines as they look very similar. Dr Chambers explained that you can't use these reports for comparison as they are not intended for that purpose.

3.12.14 Simon Terry emphasised that the benefits information relates to 'a' vaccine and not these specific vaccines. He agreed with the Agency's assessment and emphasised the importance of assessing marginal benefits rather than absolute benefits which might accrue to any vaccine.

3.12.15 The Māori Reference Group (MRG) report was highlighted by Jon Carapiet in terms of being used as a reference for the consideration. The MRG comprised of three members selected from ERMA New Zealand's Māori National Network and provided advice from a kaupapa Māori perspective to the New Zealand Racing Board and New Zealand equine Health Association on their application (GMR07001). The MRG prepared a report that analysed the application to ERMA New Zealand and Māori consultation which identified potential Māori cultural risks, cots, benefits and/or adverse impacts to the relationship between Māori culture and their traditional in relation to ancestral lands, water, sites, waahi tapu, valued flora and fauna and other taonga. Issues raised in the MRG report were addressed in the E&R report.

3.12.16 The Committee notes that the findings of this report were addressed in the Agency's E&R report and that it is publically available upon request from ERMA New Zealand.